Application for Reassessment of a Hazardous Substance under section 63 of the Hazardous Substances and New Organisms Act 1996

Name of substance: endosulfan and formulations containing endosulfan

Applicant:

Chief Executive ERMA New Zealand

Office use only	
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The application

This application is made by the Chief Executive of ERMA New Zealand for the reassessment under the Hazardous Substances and New Organisms Act 1996 of the insecticide endosulfan and of products containing endosulfan. Following a submission and hearing process, the Environmental Risk Management Authority will make a decision on the future use of endosulfan in New Zealand. The Authority's decision will be based on whether or not the positive effects (benefits) of using endosulfan outweigh the negative effects (risks and costs) of its use - after taking account of all safety precautions that might be imposed and the likely effects of the substance being unavailable.

If the benefits outweigh the risks and costs, the Authority may approve the continued use of endosulfan in New Zealand for some or all of its current uses (possibly with stricter controls or with further restrictions on use). If the benefits do not outweigh the risks or costs then the Authority may decide to prohibit it outright.

To assist in preparing this application, ERMA New Zealand has obtained information from a variety of sources both in New Zealand and overseas. In particular, information from Merial Watts (Pesticides Action Network), Horticulture New Zealand, Agronica (Makhteshim), New Zealand Sports Turf Institute, PGG Wrightson, Civil Aviation Authority and New Zealand Food Safety Authority has proven to be of considerable assistance in preparing this application.

Precautionary approach to determining risks

In the absence of New Zealand-specific exposure data, the assessment largely uses environmental and human health models to estimate exposure. These models use conservative assumptions and may overestimate risks.

This precautionary approach is consistent with the HSNO Act and regulations. These provide that where there is scientific and technical uncertainty, the Authority must consider the materiality of the uncertainty and if the uncertainty cannot be resolved to its satisfaction, must take into account the need for caution in managing the adverse effects of the substance.

Current use of endosulfan

Formulations containing endosulfan have been registered for use in New Zealand since 1963 and sold for over 50 years in more than 60 countries around the world. Endosulfan is used as a broad spectrum insecticide in many crops including cotton, soybeans, fruit tree crops and vegetables. It has excellent efficacy against a number of difficult-to-control pests, which can cause substantial crop damage and loss of yield. Because of its unique mode of action, endosulfan is used in Integrated Pest Management (IPM) and resistance management programmes.

In New Zealand endosulfan is used on a variety of crops including vegetables, berry fruit and ornamentals. It is also put to 'off-label'[1] uses including use on citrus and earthworm control on turf at golf courses, bowling clubs, parks, sports grounds, and airports.

There is evidence that endosulfan use in New Zealand has been declining over the past 10 years. This has been market driven as well as through the availability of some new insecticide chemistry. Three products using endosulfan are currently approved for use in New Zealand, but only one of the three companies has indicated it supports the continued use of endosulfan in New Zealand.

Overseas regulatory status of endosulfan

As summarised in the table below, endosulfan products have been reviewed in a number of countries. These reviews have resulted in restrictions, prohibitions or voluntary removal from the market. In the European Union, a 2005 European Commission (EC) decision required authorisations for products containing endosulfan to be withdrawn by June 2006.

Australia and the United States have restricted the use of endosulfan products. In Australia, several of the currently registered label uses in New Zealand were deleted following the APVMA review final report released in 2005. In the United States, the US EPA's review is still in progress with public consultation on updated human health and environmental risk assessments closing in February 2008.

Canada is currently re-evaluating endosulfan. A preliminary assessment released in October 2007 indicates that a number of the proposed mitigation measures are unlikely to be feasible.

The EC has also submitted a proposal to the Stockholm Secretariat that endosulfan be considered for inclusion under the Stockholm Convention on Persistent Organic Pollutants (POPs). Due to a lack of data, further discussions regarding this submission have been deferred to the next POPs Review Committee meeting in November 2008.

Further overseas action concerning endosulfan includes the recommendation from the Rotterdam Convention Chemical Review Committee (23 March 2007), that endosulfan be included in the Prior Informed Consent (PIC) procedure under the Rotterdam Convention. This recommendation was based on the grounds that endosulfan poses unacceptable risks to the environment.

Summary of overseas regulatory reviews

Country	Review Outcome
European Union	Use prohibited
United States	Restrictions imposed (review still in progress)
Australia	Some uses prohibited; restrictions imposed on others
Canada	Review in progress; preliminary mitigation measures proposed

[1] 'Off-label use' refers to the use of a product in a manner that was not assessed and approved when the product was registered under the ACVM Act, but which is lawful provided the user takes proper precautions to avoid breaches in residue standards on crops for human consumption.

Risks, costs and benefits of use in New Zealand

The risks to consumers exposed to endosulfan residues in food have not been considered by ERMA New Zealand in this reassessment. Dietary exposures and risks are evaluated by the New Zealand Food Safety Authority under the Food Act 1981.

Endosulfan is classified as acutely toxic (particularly when inhaled or absorbed through the skin) and very toxic to aquatic organisms.

The assessment of the risks, costs and benefits of the use of endosulfan in New Zealand is based on the following use scenarios:

Use scenarios evaluated in this application

Scenario	Application rate/assumptions
Label use – outdoor vegetables/berries	Maximum application rate specified on the label is 0.7 kg endosulfan a.i./ha. Frequency of use is not specified on the label, but the Agency has assumed 4 times per year with an interval of 10 days between applications. The Agency has assumed a high ground based boom sprayer with medium droplet size
Label use - glasshouse	0.7 kg a.i./ha using remote trolley sprayers or low-volume misters
Turf ('off label' use)	Maximum application rate of 2.1 kg a.i./ha, application once a year and with wetting in following application and assuming a low boom with medium droplet size
Citrus ('off label' use)	Maximum application rate of 1.3 kg a.i./ha, twice a year with an application interval of 14 days, using an airblast sprayer
Backpack/handheld sprayer (assessed for human health risks only)	0.7kg a.i./ha

Environmental risk assessment

The environmental risk assessment of the use of endosulfan in New Zealand concludes that:

- There is a high acute and chronic risk to aquatic species (fish and invertebrates) from all current uses of endosulfan in New Zealand. This conclusion is based on lower sensitivity environmental exposure modelling.
- Exposure of non-target areas, including the aquatic environment, can be reduced by the use of buffer zones. Such buffer zones would need to be substantial, possibly extending over 100 metres.

- There is a risk to earthworms when endosulfan is used in accordance with label uses. Runoff from use could lead to risks to earthworms and soil arthropods outside the application area. Endosulfan is used to control earthworm populations under specific circumstances including use on sports fields and grass areas at airports.
- Laboratory data suggests that endosulfan is toxic to bees and other non-target terrestrial invertebrates. There is uncertainty as to whether such effects occur in the field.
- There is no indication of risks to plants.
- There may be a risk to birds feeding in fields where crops have been recently treated. There is an acute risk to birds associated with the use of endosulfan on turf.
- The risk to water birds is low. Using a conservative model there is some risk to large water birds which feed exclusively on piscivorous fish.
- No assessment can be made of the risk to marine mammals (seals, dolphins) due to an absence of New Zealand-based data. However, contamination of remote regions through long-range movement of endosulfan is likely based on overseas monitoring. ERMA New Zealand has not considered this aspect of the risk of use of endosulfan as part of this reassessment. It is more appropriate for this risk to be addressed at the international level through the Stockholm and Rotterdam Conventions.

Human health risk assessment

The human health risk assessment concludes that:

- Risks to operators involved in mixing, loading and applying endosulfan for outdoor crops (including hand-held application) in accordance with current labelled application rates (0.7kg a.i./ha) are estimated as acceptable, provided that adequate personal protective equipment (PPE) is used. The required PPE includes gloves during mixing and loading; gloves, visor, hood, overalls and boots during application.
- Risks to operators involved in mixing and loading within glasshouses are acceptable provided adequate PPE is used. Risks to applicators within glasshouses have not been separately modelled but are assumed to be high. For that reason, application should be by remote automated systems.
- Risks to operators for turf and citrus applications even if full PPE (including respiratory protection) is used are high. This is due to the application rates being higher than for the current label uses for both turf and citrus and the different application method for citrus only.
- Risks to workers re-entering areas treated in accordance with label uses, including glasshouse use, are estimated to be acceptable provided appropriate PPE is used or Restricted Entry Intervals (REIs) are applied.
- Risks to bystanders and residents are estimated as acceptable for boom application to turf and in accordance with the label uses. However, risks to

bystanders and residents from air-blast application to citrus are estimated as very high at current application rates and procedures.

- Risks to sports people from use of endosulfan on treated turf are acceptable if application is in accordance with the current standard practices involving watering in and only one annual treatment and an REI is applied (in the case of "ground contact" sports such as rugby, football or hockey and public parks where children may play).

Risks to society and communities

The review of the risks to society and community concludes that there is a potential effect of increased anxiety in people who are concerned about the continued use of endosulfan in New Zealand while its use has either been banned or severely restricted in other jurisdictions. The size and expression of this effect cannot be fully assessed at this stage.

Risks to the market economy

The review of the risks to the New Zealand market economy concludes that:

- While there may be adverse effects on trade from consignments being rejected because endosulfan has been used, this risk can be managed by industry.
- There is the potential for an adverse effect on New Zealand's 'clean green' image.

Relationship of Māori to the environment

The impact from the use of endosulfan on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna and other taonga is assessed to be moderate provided controls are complied with. However, in the absence of good information about benefits Māori may have concerns about the ongoing use of endosulfan.

Assessment of benefits

The environmental benefit assessment concludes that there are no verifiable potentially significant beneficial effects on the environment.

The human health benefit assessment concludes that there may be a potential indirect beneficial effect on human health and safety from the use of endosulfan at airfields. Endosulfan is currently used to remove earthworms and reduce the risk of birdstrike.

The assessment of the benefits to society and community concludes that:

- There is a beneficial effect to farmers, horticulturalists and turf managers from knowing that endosulfan is available as a 'backstop' product or insecticide of last resort.
- An indirect effect of the use and availability of endosulfan for controlling earthworms, is the reduced risk of playing fields being closed.

The assessment of the benefits to the market economy concludes that:

- There are direct economic benefits to agriculture and horticulture. Endosulfan is viewed as an insecticide of last resort in the horticulture industry which can salvage some value from a crop that would otherwise be worthless.
- Endosulfan is considered by turf managers to be the most effective product for controlling earthworms.

Preliminary recommendations

The recommendations set out below are preliminary only. An important part of the reassessment process is public submissions on the application. These public submissions are likely to have an effect on the final outcome of the reassessment.

On the basis of its evaluation of whether the risks associated with the use of endosulfan in New Zealand outweigh the benefits, ERMA New Zealand proposes the following preliminary recommendations to ensure that practices are safe for people and the environment:

1. That the use of endosulfan be prohibited for:
    - aerial and domestic use of the substance on the basis that these are not uses to which it is currently put (and the relevant risks have not been assessed as part of this application); and
    - airblast application for citrus on the basis that risks to operators and bystanders are currently assessed as very high.

2. That use on turf be restricted to one annual treatment, followed immediately by watering in, with no use of the treated area in the case of "ground contact" sports use and public parks where children may play, for a period of at least 48 hours following treatment (noting, however, that the operator exposures are high even with full PPE, so the feasibility of a lower application rate needs to be explored).
3. That the following Restricted Entry Intervals (REIs) be imposed for other uses, where PPE is not used when re-entering:
    - 48 hours for all crops not listed below;
    - 3 days for sweetpotato, mustard, radish, turnip;
    - 4 days for brassicas (broccoli, cabbage, cauliflower, brussels sprouts);
    - 6 days for blueberries;
    - 10 days for sweetcorn.

    In respect of the issue of REIs, ERMA New Zealand notes that:

- although re-entry restrictions can be specified on New Zealand labels under HSNO regulations, the clearer, more prescriptive approach recommended above is in line with requirements introduced by overseas agencies;
- consideration will need to be given to an appropriate REI for greenhouse use;
- consideration will need to be given to longer REIs in the case of 'pick your own' berry orchards to take account of the exposure of pickers; and
- REIs may not be necessary in respect of post-application turf maintenance activities (for example, mowing/rolling) unless the work involves direct exposure.

4. That a no-spray buffer zone around waterbodies and the edges of treated crops be introduced due to high level of risks to the aquatic environment and to soil fauna (ERMA New Zealand currently considers a 100 m buffer zone may be appropriate on the basis of overseas' analyses of the effectiveness of buffer zones).
5. That reduced (maximum) application rates (kg a.i./ha per application/season) and/or limits on the number of applications (for example, per season) be introduced for some uses in order to lower the risks to the environment and people (noting the measures of this type proposed by some overseas agencies).
6. That suitable PPE be stipulated for different types of application and at different stages of the lifecycle (mixing/loading; application).

Finally, if the Authority's overall evaluation favours retention of some or all of the endosulfan approvals, ERMA New Zealand **recommends** the following classification changes:

- for all formulations, replace 6.1C overall acute toxicity classification with 6.1A based on inhalation toxicity;
- replace the current 6.3B classification on Substance D with a 6.3A classification;
- remove the 6.8B classification applied to Thionex Insecticide Solvesso formulation;
- replace the current 9.2C classification on endosulfan and all its formulations with a 9.2A classification;
- assign an approval number to the Thionex Insecticide Solvesso formulation;
- change the packing group assigned to endosulfan and all formulations containing endosulfan from PG I to PG II.

Submissions

Submissions are now invited on the appropriateness or workability of the above recommendations. In particular, ERMA New Zealand would like information on the following:

1. What alternative substances are available, how effective are they and what risks, costs and benefits are associated with their use in New Zealand?

2. Can the application rate (0.7 kg a.i./ha) or frequencies for label use be reduced without compromising efficacy?

3. Can the application rate used on turf (2.1 kg a.i./ha) be reduced without compromising efficacy, in order to reduce operator exposure (when using full PPE) to acceptable estimates?

4. In order to reduce health risk to operators, most uses require the use of "full" PPE consisting of gloves, face shield during mixing loading and gloves, overalls, hat and boots during application. If this level of PPE were made mandatory, would continued use of the product be feasible?

5. Re-entry risks for workers (and 'pick your own') are estimated as high for horticultural applications since these personnel do not generally use PPE. In this case, REIs represent an important means of addressing these exposure risks. Are the REIs set out above feasible?

6. What would be the effect of a mandatory 48 hour closure period after one annual turf application and watering in for "ground contact" sports, such as rugby, football or hockey and use on public parks where young children may play?

7. What would be the effect of a mandatory 100 m (or more) buffer zone to reduce exposure to non-target areas including the aquatic environment?

Submissions on this application must be made within a 30 working day period. Electronic responses using the form on our web site are encouraged. Please return your submission, whether electronic or by post, fax or email to:

ERMA New Zealand
PO Box 131
Wellington
Fax: 04 914 0433
Email: Samantha.smith@ermanz.govt.nz
www.ermanz.govt.nz
Please mark all submissions for the attention of: Samantha Smith.

All submissions must be received by 5 pm, Friday, 8 August 2008.

Submissions must state the reasons for making the submission and state whether the submitter wishes to be heard at a public hearing. The submission may also state any decision sought.

Section One – Applicant Details

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Section Two – Application Type and Related Approvals

2.1 Application type

2.1.1 This is an application for the reassessment of endosulfan and formulations containing endosulfan prepared by the Chief Executive of ERMA New Zealand ('the Agency') under section 63 of the Hazardous Substances and New Organisms Act ('the Act').

2.1.2 Endosulfan was placed on the Chief Executive's Reassessment Priority List in 2006, taking into account:

- Public concern about the use of pesticides, due to their association with adverse effects in humans and the environment. An example of this was listing as a Priority 1 pesticide for Reassessment, in Petition 1999/227 of Kees Bon, presented to the Local Government and Environment Select Committee, September 2006.
- Overseas action including banning, voluntary removal from markets and stricter controls applied by some regulatory agencies.
- Recommendations to include in the Rotterdam Convention Prior Informed Consent (PIC) procedure and to include under the Stockholm Convention as a persistent organic pollutant (POP).

2.1.3 In June 2007, the Environmental Risk Management Authority ('the Authority') considered whether or not there were grounds for reassessing the approvals for endosulfan and formulations containing endosulfan, under section 62 of the Act.

2.1.4 The Authority decided that there were grounds for reassessment based on sections 62(2)(a) and 62(2)(b) of the Act, namely that:

62(2)(a) Significant new information relating to the effects of endosulfan has become available.

62(2)(b) Other substances with similar or improved positive effects and reduced adverse effects are available.

2.1.5 The decision was notified on 19 June 2007. In reaching its decision the Authority noted the following:

- Formulations containing endosulfan have been registered for use in New Zealand since 1963. Currently, three products are registered for agricultural use in New Zealand (Thiodan, Flavylan 350EC and Thionex Insecticide).
- Endosulfan has been voluntarily removed from the market in several countries and also banned in plant protection products in a number of other countries. Australia, Canada and the US have all reassessed the use of endosulfan restricted its use and put in place measures to

mitigate worker and environmental risks. In a number of areas these measures impose tighter controls than the current HSNO controls.

- The Rotterdam Convention Chemical Review Committee, 23 March 2007, recommended that endosulfan be included in the PIC procedure under the Convention. This recommendation was based on the grounds that endosulfan poses unacceptable risks to workers and the environment.
- There are less hazardous alternatives to endosulfan available.
- The reassessment of endosulfan and formulations containing it aligns with the principles of ERMA New Zealand's Risk Reduction Strategy.

2.1.6 The Authority considered that there is new information from overseas regulatory authorities relating to the effects of endosulfan and that, in the light of this new information, reassessment of the substance is warranted. The Authority acknowledged that there are alternatives to endosulfan, adding weight to the justification for a reassessment of the substance. In addition, it considered that a reassessment of endosulfan and its formulations aligns well with the Authority's Risk Reduction Strategy, which seeks to reduce the risks New Zealanders may be exposed to via hazardous substances.

2.1.7 This application has been prepared by the Agency and will be publicly notified for submissions for a minimum 30 working day period. The submissions received, together with the application, will be taken into account by the Authority in considering the reassessment. If required by any submitter, the Authority will hold a public hearing.

2.2 Sources of information for this application and consideration of uncertainty

2.2.1 Clause 8 of the Hazardous Substances and New Organisms (Methodology) Order 1998 (the Methodology) states that the information used by the Authority when considering an application must be relevant and appropriate to the scale and significance of the risks, costs and benefits associated with the substance.

2.2.2 Clause 29 of the Methodology indicates that when the Authority encounters scientific and technical uncertainty relating to the potential adverse effects of a substance, the Authority must determine the materiality and significance to the application of the uncertainty. Where any scientific or technical uncertainty is not resolved, the Authority must take into account the need for caution in managing the adverse effects of the substance (clause 30).

2.2.3 Where the Authority considers that there is uncertainty in relation to costs, benefits, and risks (including, where applicable, the scope for managing those risks), the Authority must attempt to establish the range of uncertainty

and must take into account the probability of the costs, benefits and risks being either more or less than the levels presented in evidence (clause 32).

2.2.4 Because it did not have sufficient information of its own to inform the preparation of this application, the Agency circulated a draft of the application for the purpose of gathering additional information in the following areas:

- use patterns – ie how widespread is the use of endosulfan and to what crops it is applied;
- 'off label' uses;
- benefits from the use of the substance in New Zealand;
- inclusion in resistance management programs;
- lifecycle information.

2.2.5 A full list of the parties contacted for this information is set out in Appendix J. In response to this 'pre-notification' consultation, information was received from the following sources:

- Agronica (Makhteshim)
- Pesticide Action Network Aotearoa New Zealand
- Horticulture New Zealand
- New Zealand Sports Turf Institute
- PGG Wrightson
- Civil Aviation Authority
- New Zealand Food Safety Authority.

2.2.6 In addition, the Agency considered, to the extent appropriate, the numerous publicly available sources of toxicology and environmental fate and effects test data, studies and other references listed on pages 152-159.

2.2.7 Only one of the registrants of endosulfan formulations has provided information in support of the continued use of endosulfan in New Zealand. Where appropriate, this is identified throughout this application. The other registrants have indicated that they no longer wish to support the use of this product in New Zealand and that they will be voluntarily phasing out this product from their product lines. Nevertheless, this application considers all formulations with current HSNO approvals.

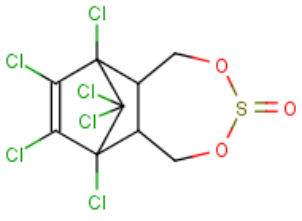
Section Three – Information on the Substances

3.1 Identification of the substances

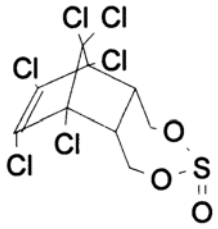
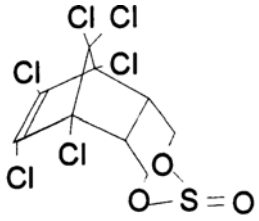
3.1.1 **Substance Names:** The existing substances for which there are HSNO approvals and which are therefore the subject of this reassessment, are as follows:

- Endosulfan (HSR002846).
- Emulsifiable concentrate containing 350 g/litre endosulfan (Substance A) (HSR000679).
- Emulsifiable concentrate containing 350 g/litre endosulfan (Substance B) (HSR000678).
- Emulsifiable concentrate containing 350 g/litre endosulfan (Substance C) (HSR000487).
- Emulsifiable concentrate containing 350 g/litre endosulfan (Substance D) (HSR000677)[2].

Table 1: Identification of endosulfan

Common Name	Endosulfan
CAS Index Name	6,9-Methano-2,4,3-benzodioxathiepin, 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-, 3-oxide
Synonyms	Endosulphan 5-Norbornene-2,3-dimethanol, 1,4,5,6,7,7-hexachloro-, cyclic sulfite
CAS Registry Number	115-29-7
Molecular Formula	$C_9H_6Cl_6O_3S$
Molecular Weight	406.96 g/mol
Structural Formula	

[2] Note - the current ERMA New Zealand classification reflects the xylene-based endosulfan formulation (the change to the Solvesso formulation for Thionex 350 EC was notified to ERMA New Zealand on 27 October 2004) and the correct classification should be applied to reflect the Solvesso-based product (as presently registered by ACVM, P07281.

Sterioisomers	alpha(α) endosulfan (1) stereochemistry 3α, 5aβ, 6α, 9α, 9aβ comprises 63-70% of the technical grade  beta (β) endosulfan (II) stereochemistry 3α, 5aα, 6β, 9β, 9aα comprises 28-31% of the technical grade 
Metabolites	Endosulfan sulphate – main metabolite in soils, biological degradation in water and some mammals Endosulfan diol – hydrolysis in water Endosulfan ether – oxidation of the diol Hydroxyl endosulfan ether – oxidation of the diol Endosulfan lactone – oxidation of the diol
Common Impurities in Technical Grade Endosulfan	Endosulfan alcohol Endosulfan ether Hexachlorocyclopentadiene Residual solvent

3.1.2 While all four approved emulsifiable concentrates contain 350 g/litre endosulfan the excipient components differ giving each substance a unique HSNO classification (see Table 4).

3.1.3 **Trade names:** This application for reassessment covers all substances fitting these definitions and includes the following trade name products:

- Thiodan (Bayer New Zealand Ltd) 350 g/L endosulfan;
- Flavylan 350EC (Adria New Zealand Ltd) 350 g/L endosulfan; and
- Thionex Insecticide (Agronica New Zealand Limited) 350 g/L endosulfan.

3.1.4 The endosulfan products are all emulsifiable concentrates. The full compositions of the substances are contained in confidential Appendix L.

3.1.5 There is currently no product registered with ACVM matching the substance description "Emulsifiable concentrate containing 350 g/litre endosulfan (Substance A)." The ACVM registration for the product that was given an approval upon 'transfer' to the HSNO regime in 2004 under this

description, Endo 350EC, was cancelled on 3 May 2006, although old stock may still be in use. It is also still legal to use the old formulation for non-agricultural compound use.

3.2 Chemical and physical properties of endosulfan and its formulations

3.2.1 The chemical and physical properties of endosulfan and the formulated substances are shown in Table 2.

Table 2: Chemical and physical properties of endosulfan products

Substance	**Endosulfan**	**Endo 350 EC (350 g/litre endosulfan) Substance A**	**Flavylan 350EC (350 g/litre endosulfan) Substance B**	**Thiodan (350 g/litre endosulfan) Substance C**	**Thionex 350 EC (350 g/litre endosulfan) Substance D[1]**	**Thionex 350 EC (350 g/litre endosulfan) Solvesso Formulation[2]**
Appearance (colour, odour, physical state or form)	Physical state: solid Colour: off white powder; white crystalline solid Technical endosulfan flakes with a tendency to agglomerate; cream to tan mainly beige, yellow crystalline solid; beige slightly yellow granules Odour: has been described as being like sulphur dioxide or odourless	Physical state: liquid	Physical state: liquid	Physical state: liquid	Physical state: liquid Colour: tan Odour: specific odour of solvent	Colour: Clear pale yellow to amber liquid Odour: slight aromatic odour
pH			5.8	Approx 6		6.6 – 8.0
Density	1.745 g/cm^3 at 20^{o}C 1.87g/cm^3 at 20^{o}C (purified endosulfan)		1.066-1.073	1.08	1.06-1.08 @ 20^{o}C	1.072 – 1.078 @ 20^{o}C
Vapour pressure	α endosulfan = 1.05 x 10^{-3} Pa β endosulfan = 1.38 x 10^{-4} Pa					0.3 kPa (at 38 C) -solvent
Melting / Boiling point	α endosulfan = 109.2 ^{o}C β endosulfan = 212-213^{o}C mixture of isomers = 76-124^{o}C					
Solubility in water	α endosulfan = 0.41 mg/l β endosulfan = 0.23 mg/l					
Flash point		34^{o}C	minimum 45^{o}C	> 64^{o}C		>65^{o}C
Octanol/Water partition log Kow	α endosulfan = 4.94 at pH 4, 20^{o}C 4.77 at pH 7, 20^{o}C 5.64 at pH 10, 20^{o}C β endosulfan = 4.87 at pH 4, 20^{o}C 4.55 at pH 7, 20^{o}C 5.65 at pH 10, 20^{o}C					

[1] These properties apply to the original formulation containing xylene.

[2] Additional column to show the properties of the Thionex Solvesso formulation.

3.3 Review of hazardous properties of endosulfan and endosulfan formulations

Classification

3.3.1 A summary table of the classification of endosulfan and the formulations appears in Tables 3 and 4 respectively. A more detailed description of the data underlying the classification, including endpoints for which classification is not triggered, is included in Appendices A and B.

Table 3: Summary of classifications for endosulfan

Toxicity Classification	Classification	Data triggering classification	Reference
Acute Oral Toxicity	6.1B	SPECIES: Rat ENDPOINT: LD_{50} VALUE: 22.7 mg/kg b w	APVMA, 1998
Acute Dermal Toxicity	6.1B[1]	SPECIES: Rat ENDPOINT: LD_{50} VALUE: 34 mg/kg b w	Lewis, 1996
Acute Inhalation Toxicity	6.1A	SPECIES: Rat (F) ENDPOINT: LC_{50} VALUE: 13 mg/m^3 (= 0.013 mg/L)	APVMA, 1998
Overall Acute Toxicity	6.1A	Acute Inhalation Toxicity	
Eye Irritation	6.4A	R-PHRASE: R 36 'Irritating to eyes.'	APVMA 1998
Target Organ Systemic Toxicity	6.9A	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).	APVMA, 1998
Aquatic ecotoxicity	9.1A	freshwater fish 96 hr LC_{50} = 0.2 µg/l freshwater invertebrates48 hr EC_{50} = 0.1 µg/l	most sensitive species ANZECC, 2000
Soil ecotoxicity	9.2A	*Eisenia andrei* (Earthworm) 14 day(s) EC_{50} of 0.94 mg/kg-dry-weight-soil	Heimbach, 1985
Terrestrial vertebrate ecotoxicity	9.3A	SPECIES: Rat ENDPOINT: LD_{50} VALUE: 22.7 mg/kg b w	APVMA, 1998
Terrestrial invertebrate toxicity	9.4B	SPECIES: Honey bee *Apis mellifera* DURATION: 48 hr ENDPOINT: LD_{50} VALUE: 2 µg a.i./bee (oral), 2.4 µg a.i./bee (contact)	APVMA (1998)

[1] See Paragraph.3.2.2.

Table 4: Summary of classifications for endosulfan formulations

Toxicity Classification	Emulsifiable concentrate containing 350 g/l endosulfan				
	(Substance A)	(Substance B)	(Substance C)	(Substance D)	MCW: Thionex Insecticide (350 g/L endosulfan) Solvesso formulation
Flammability	3.1B	3.1C	3.1D	3.1C	3.1D
Acute Oral Toxicity	6.1C	6.1C	6.1C	6.1C	6.1C
Acute Dermal Toxicity	6.1B	6.1B	6.1B	6.1B	6.1B
Acute Inhalation Toxicity	6.1A	6.1A[1]	6.1A[1]	6.1A[1]	6.1A[1]
Overall Acute Toxicity	6.1A	6.1A	6.1A	6.1A	6.1A
Skin Irritation	6.3A	6.3B	6.3A	6.3A[2]	6.3A
Eye Irritation	6.4A	6.4A	8.3A	6.4A	6.4A
Skin Sensitisation	6.5B				
Reproductive Toxicity	6.8B			6.8B	
Target Organ Systemic Toxicity	6.9A	6.9A	6.9A	6.9A	6.9A
Aquatic ecotoxicity	9.1A	9.1A	9.1A	9.1A	9.1A
Soil ecotoxicity	9.2A	9.2A	9.2A	9.2A	9.2A
Terrestrial vertebrate ecotoxicity	9.3B	9.3B	9.3B	9.3B	9.3B
Terrestrial invertebrate toxicity	9.4B	9.4B	9.4B	9.4B	9.4B

[1] See Paragraph 3.3.3.

[2] See Paragraph 3.3.4.

Issues with classification

3.3.2 The data used to assign HSNO classifications have been compared with the data used to classify overseas. The toxicity and ecotoxicity values used to classify are sometimes slightly different, with the exception of the value used to classify as 6.1 dermal toxicant under HSNO, 34 mg/kg bw, which appears to be well below the range of the internationally accepted values. The most widely accepted value is 500 mg/kg body weight which would trigger a 6.1D classification. However, the real worker exposure testing carried out for the APVMA review showed that the 500 mg/kg bw LD_{50}

assigned to endosulfan was not a true indication of the effects, and that the results indicated that the LD_{50} should be lower than 500 mg/kg bw. Due to these uncertainties the 6.1B classification for endosulfan has been retained, and the lower LD_{50} value (34 mg/kg bw) has been used to derive the classification of the formulated products using the mixture rules (see Appendix A).

3.3.3 When the endosulfan formulations were first approved a 6.1A inhalation classification was not applied because when sprayed the formulation has been diluted. Current policy is that this is not relevant as there are also risks to operators during mixing and loading. Following review of the acute inhalation toxicity data for endosulfan formulations these have been assigned a 6.1A inhalation classification and therefore an overall classification of 6.1A for the acute toxicity (6.1) subclass. In the absence of data to determine whether or not endosulfan formulations produce a mist under their conditions of use the 6.1A classification applies. The Agency has extrapolated somewhat in the calculation of 6.1A as endosulfan was tested as a dust, and this dust LC_{50} has been applied to calculate an LC_{50} for the endosulfan formulations as a mist.

3.3.4 The current classification of 'Substance D' is 6.3B. The classification is based on a component of this formulation (xylene). Xylene's classification has been changed since transfer into the HSNO regime of endosulfan formulations from 6.3B to 6.3A. Applying the mixture rules (ERMA, 2008) results in an overall classification of 6.3A for Substance D.

3.3.5 A number of submissions received, from the initial consultation of the Chief Executive's Reassessment Priority List in 2006, made claims that endosulfan was carcinogenic. Endosulfan has not been classified as a carcinogen by the Agency. This accords with the other regulatory agencies assessments reviewed. Endosulfan is not listed by the International Agency for Research on Cancer (IARC) as a carcinogen. Reports by Health Canada Pest Management Regulatory Agency (2007), European Union (2007), United States Environmental Protection Agency (2002) and the Agency for Toxic Substances and Disease Registry (2000) have all concluded that endosulfan is not carcinogenic.

3.3.6 The 9.2 classification for endosulfan shown in Tables 3 and 4 differs to that of the approved substances – 9.2C has been replaced by a 9.2A classification, since the 9.2C classification was erroneously assigned upon transfer to the HSNO Act. As endosulfan is the only component in the products that has a 9.2 classification, the 9.2A arises solely from the endosulfan component of the products. The supporting data of 14 d LC_{50} of 9 mg/kg dry weight soil supports a 9.2A classification as a safety factor of 10 is incorporated to represent the extrapolation from a LC_{50} value to an EC_{50} value (EC_{50} = 0.94 mg/kg dry weight soil).

3.3.7 Internationally there is no agreement on whether or not endosulfan is an endocrine disruptor. However, endosulfan has been included in the OSPAR Commission List of Potential Endocrine Disruptors. Nor is there agreement internationally on the definition of endocrine disruption. Under the HSNO

framework there is no definition or a classification category specifically for endocrine disruptors. Endocrine disruption is considered a mode of action rather than an effect. A specific effect needs to be shown before a HSNO classification can be applied. Currently therefore ERMA New Zealand has not classified endosulfan as an endocrine disruptor.

3.4 Lifecycle of endosulfan formulations

3.4.1 Of the companies currently importing/manufacturing endosulfan formulations, the Agency has been informed that only Agronica (Makhteshim Chemical Works, MCW) wishes to support the continued use of endosulfan in New Zealand. The description of the lifecycle of endosulfan is based on information by MCW.[3]

3.4.2 Until such time as companies other than Agronica cancel their ACVM registrations, they can continue to market their approved endosulfan formulations into the agricultural market. The Agency has assumed that the lifecycle determined from Agronica information will apply to all formulations.

3.5 Manufacture

3.5.1 MCW endosulfan formulations are not currently manufactured in New Zealand.

Importation

3.5.2 MCW endosulfan formulations are imported to New Zealand distribution sites in 10 litre HDPE drums. Quantities are imported in shipments of around 5,000L.

Repackaging/storage

3.5.3 Shipping containers are devanned and drums are labelled at point of manufacture for distribution in New Zealand.

Transport

3.5.4 Transport is in compliance with the Land Transport Rule: Dangerous Goods Rule.

3.5.5 Endosulfan is classified as a Class 6.1 Toxic Substance Packaging Group II and therefore a consignment must be accompanied by a Dangerous Goods Declaration and must not to be loaded on the same vehicle as Class 1 Explosives or Food Items (unless transported in a segregation device) and must be separated by 3 metres from Class 5.1 Oxidising Substances and Class 5.2 Organic Peroxides.

[3] MCW communication dated 29 February 2008.

3.5.6 In addition, for quantities greater than 50L, consignments must be placarded according to Section 9 of the Rule.

3.5.7 The Agency notes that under the HSNO Packaging Regulations, a 6.1A classification triggers Packaging Group I. The HSNO Packaging Regulations for 6.1 inhalation classifications is not in line with the UN recommendations for the transportation of dangerous goods. It is proposed that the default Packing Group I is varied to a Packing Group II in line with currently accepted international packaging requirements for endosulfan and formulations containing endosulfan. The WHO International Chemical Safety Card (ICSC 0742) for endosulfan assigns a PGII.

Disposal

3.5.8 Empty drums are triple rinsed and delivered by end users to one of 52 District Council approved "Agrecovery" recycling sites.

Use of endosulfan

3.5.9 Only emulsifiable concentrate formulations containing 350 g/l endosulfan are approved and available in New Zealand.

3.5.10 The Agency is aware that formulations containing endosulfan are put to several uses in New Zealand that are not specified on the label. This 'off-label' use is lawful if in accordance with ACVM Group guidance (ACVM, 2006):

'Off-label use' refers to the use of a product in a manner and/or on a species of animal or plant that was not assessed and approved when the product was issued its official marketing approval. In New Zealand the official marketing approval is a product registration from the Approvals and ACVM Group of NZFSA or a prescribed exemption from registration. The uses recommended by the registrant of the product and approved by the Group are always provided on the label. Consequently, any use not listed on the label is called an off-label use.

The ACVM Group (has) addressed the problem (of minor use/minor species) by providing a general registration condition that allows off-label uses, provided the user takes proper precautions to avoid breaches in residue standards.

3.5.11 The Agency has evaluated the off-label uses of which it is aware (turf, airblast spray to citrus, glasshouse use) or that seem likely (back-pack application), but acknowledges that there could be other off-label uses of which it is unaware.

3.5.12 The Agency understands that no endosulfan formulations are sold on the New Zealand domestic market and that aerial application does not take place in New Zealand. These potential uses have not therefore been evaluated further.

Label use

3.5.13 The label application rates for all the currently registered endosulfan formulated products are identical. The application rates are as follows:

Table 5: Current application rates for endosulfan

Vegetable/fruit	Rate
Tomatoes	120-200mL or 1.2-2 L/ha (equivalent to 420-700 g a.i/ha)
Potatoes	200mL or 2 L/ha (equivalent to 700 g a.i/ha)
Cabbage, cauliflower and other vegetable brassicas	120-200mL or 1.2-2 L/ha (equivalent to 420-700 g a.i/ha)
Fodder crop seedlings	150mL or 1.5 L/ha (equivalent to 525 g a.i/ha)
Maize and sweetcorn	200mL or 2 L/ha (equivalent to 700 g a.i/ha)
Strawberries	150-200mL or 1.5-2 L/ha (equivalent to 525-700 g a.i/ha)
Blackberries, boysenberries, raspberries	200mL or 2 L/ha (equivalent to 700 g a.i/ha)
Gooseberries, blackcurrants	200mL or 2 L/ha (equivalent to 700 g a.i/ha)
Ornamentals (glasshouse and outdoors)	200mL or 2 L/ha (equivalent to 700 g a.i/ha)

3.5.14 The maximum use rate specified on any of the labels is 0.7 kg a.i./ha. Frequency of use is not specified on the labels, but the Agency has assumed a frequency of 4 times per year with an interval of 10 days between applications. This assumption is based on a thrip control strategy on onions forwarded to the Agency by Horticulture New Zealand (P. Ensor pers.comm.), that specifies that each product used in the strategy should be used 3-4 times to reduce a whole generation of thrips. The Agency has assumed that such applications will be made with a high boom and a medium spray droplet size.

'Off-label' use

3.5.15 In addition to the usage outlined above, the Agency has been notified of two off-label uses of endosulfan:

- On turf (for example, sports fields, golf courses, bowling greens, airport grassed areas) with a maximum application rate of 2.1 kg a.i./ha, application once a year and with wetting in following application (B. Walmsley pers. comm.). The Agency assumes a low boom would be used for such applications. In the past, a pelleted endosulfan formulation was used for airport earthworm control and this would be the favoured formulation if authorised (R. Bodell pers. comm.). Currently no pellet formulation is authorised in New Zealand.

- On citrus with a maximum application rate of 1.3 kg a.i./ha (150mL per 100L, 1500 - 2500L per ha); twice a year, August to March, with an application interval of 14 days or more usually 4-8 weeks, using an airblast sprayer (S. Minchin, pers. comm.).

3.5.16 In its evaluation, the Agency has also considered human exposure from hand-held application since it considers this is likely to occur.

3.5.17 During pre-notification discussions with current manufacturer/importers of endosulfan formulations the Agency has been informed that only Agronica/MCW is prepared to continue supporting endosulfan formulations in New Zealand, but MCW proposes an amended label listing use only on tomatoes, potatoes, cabbage, cauliflower, broccoli, gooseberries, blackcurrants, and ornamentals (out of doors only).

Volumes used

3.5.18 Horticulture New Zealand has estimated the total endosulfan market in New Zealand to be in the vicinity of 15 to 20,000 litres per year (approximate figure for 2007 estimated from discussion with key industry players – P. Ensor pers. comm.). This figure is very seasonal and because endosulfan is used in response to pest levels, and in a number of cases as a measure of last resort, year on year usage can differ greatly depending on climatic conditions and pest pressure.

3.5.19 Recent endosulfan sales trends seem to indicate a decrease in the overall use of endosulfan. The main causes of this are twofold. Firstly many export markets are dictating chemical requirements (for example, onions destined for UK and Europe cannot be treated with endosulfan). The second reason is the use of new generation alternative chemicals. In particular long lasting seed treatments and selective insecticides can take the place of endosulfan (P. Ensor pers. comm.).

3.5.20 The volume of endosulfan used internationally has been estimated to peak at 13000 tonnes in 2001, with a decline since 2002 due to the introduction of new products and a phasing out from some markets (Mackay & Arnold, 2005). Worldwide it is used mainly on cotton (50%), field crops, plantation crops, soybeans (each 15%) and vegetables (5%) (Mackay & Arnold 2000).

Registered uses

3.5.21 Table 6 below shows the current registered uses for Thionex 350 EC.

Table 6: Registered uses for Thionex 350EC

Crop	Pest
Tomatoes	Aphids, Thrips, Green vegetable bug, Whitefly, Cutworms and other caterpillars
Potatoes (both table and seed potatoes)	Potato tuber moth, Aphids, Green looper caterpillar
Onions (except spring onions)	Onion thrips
Cabbage, cauliflower and other vegetable brassicas	Aphids, Diamond-back moth and White butterfly caterpillars
Fodder crop seedlings (turnips, swedes, choumoellier, feed rape, fodder-beet, mangolds) Also brassica vegetable seedlings	Nysius bug (*Nysius huttoni*)
Maize and sweetcorn (seedlings)	Cutworm
Strawberries	Aphids, Cyclamen (strawberry) mite
Blackberries, Boysenberries, Raspberries	Aphids, Bronze beetle, Redberry mite
Gooseberries, Blackcurrants	Aphids, Bronze beetle, Currant bud mite
Ornamentals (glasshouse and out of doors)	Cyclamen mite, Aphids

Report on the use of endosulfan in New Zealand provided by Horticulture New Zealand:

3.5.22 A report was provided to the Agency by Horticulture New Zealand[4] as part of the 'pre-notification' request for information from interested parties, which included the following approximate breakdown of sector use in New Zealand:

Table 7: Percentage use of endosulfan in different sectors

Crop	% Use
Outdoor Vegetable	35 – 40
Greenhouse Production	30
Turf	10 -15
Berry Fruit	10
Ornamentals	5 – 15
Citrus	1
Other	?

Outdoor Vegetable Production

3.5.23 Horticulture New Zealand further advised that, outdoor vegetable production uses the greatest amount of endosulfan, accounting for approximately 30 to 40% of total endosulfan sales. Dependence on

[4] Horticulture NZ: Endosulfan Use in New Zealand, February 2008.

endosulfan in the vegetable market is mixed, with greater use in regions with more intensive production and higher pest pressure. The vegetable crop with the largest use of endosulfan is potatoes in the Northern half of the North Island.

3.5.24 The use of endosulfan in outdoor vegetable production is mixed. Crops such as onions, potatoes and brassicas all have a range of alternative insecticide options available and although endosulfan is not used routinely by all growers, those contacted by Horticulture New Zealand in the preparation of its report were strongly of the view that endosulfan needs to be maintained as an option. This need was illustrated during the recent hot dry summer, when potato tuber moth numbers were particularly high. Growers facing this extreme tuber moth pressure had to increase chemical insecticide applications to safeguard their crops. As a result, certain regions (for example, Pukekohe, Waikato) used more endosulfan than in a 'normal' year. Growers choose to use endosulfan because they know it will work and it provides another choice of chemical group (mode of action) for resistance management purposes.

3.5.25 Endosulfan use in onion crops has been declining in recent years because of constraints placed on growers by customers. In particular, certain markets such as Europe and the UK do not accept onions that have been grown using endosulfan. However growers and industry representatives contacted by Horticulture New Zealand in the preparation of its report also expressed a desire to maintain the ability to use endosulfan should the need arise. The threat of Iris Yellow Spot Virus (Tospovirus) was put forward as another important reason why endosulfan should remain available to onion growers. This virus would have a major impact on onion crop yields and could potentially be devastating for the onion seed industry. Thrips are the known vector for this virus. When a situation arises that requires immediate control of onion thrips because of this virus, the use of endosulfan may be critically important.

3.5.26 Brassica growers advised Horticulture New Zealand that they have a range of insecticide options available and use of endosulfan in this area has also been declining in recent years due to new product availability and IPM practices. However, when these measures fail or conditions such as the recent hot dry summer produce extreme pressure, it is important to have endosulfan available as a backstop for the control of Diamondback moth and White butterfly caterpillar. Endosulfan use was critical for some growers last season and for this reason brassica growers advised Horticulture New Zealand that they do not want to see any changes to the registration of endosulfan that would limit their choices and ability to prolong the life of other chemistry through careful resistance management.

3.5.27 Endosulfan is not routinely used in maize and sweetcorn.

Greenhouse Vegetable Production (e.g. tomatoes, capsicum, courgette)

3.5.28 Greenhouse vegetable growers employ a range of control techniques including hygiene and natural predators to control insect populations.

However, even with the best management systems in the world, pest outbreaks do occur – in particular whitefly.

3.5.29 When whitefly numbers get out of control, Horticulture New Zealand advises that endosulfan is the most effective product available. It is used only when absolutely needed because bees must be removed for three days (which equates to loss of production), but growers know it will work and that whitefly numbers will be lowered to levels where other control options become effective again (for example, En-Force biological parasites).

Berry Fruit

3.5.30 Horticulture New Zealand advises that boysenberry and strawberry growers use endosulfan to control specific mite issues and that this group would be severely disadvantaged if endosulfan was not available as there are no effective alternatives. The following bullet points have been taken verbatim from Horticulture New Zealand's report:

- ***Boysenberry*** *– Boysenberry growers have a particular pest problem called Red Berry Mite. This mite lives in the buds of flowers and causes the fruit to not ripen. Endosulfan used strategically in one application can reduce Red Berry Mite numbers below an economic threshold for up to three years.*
- *Geoff Langford of HortResearch in Lincoln is working on this problem and can demonstrate that there are currently no effective alternatives to endosulfan, but that strategic timing and use of one endosulfan application can reduce Red Berry Mite numbers to such low levels that it takes between two and three years for the population to get back up to damaging levels (when the next endosulfan application is required).*
- *Alternative control strategies and chemical options are being sought but the cost and time involved with this research (and eventual registration) means that endosulfan will be relied upon by Boysenberry growers for some years to come.*
- *This is a clear example of a niche strategic application of endosulfan where growers are using the product wisely to maximum benefit. If endosulfan was not available Boysenberry growers would have no effective control measures for Red Berry Mite and livelihoods would be placed at risk.*
- ***Strawberry*** *– Strawberry growers are using endosulfan in specific instances where Cyclamen Mite is a problem.*
- *A recent programme targeting the health and hygiene of strawberry transplants has been very successful and has seen the need for endosulfan use in strawberries reduce. However where plants are carried over for a second season (a common practice in the South Island) and when outbreaks do occur, endosulfan is the only effective control measure available to growers.*

- *Once again endosulfan use is targeted and only applied when the Cyclamen Mite becomes an economic threat. The other miticide product that is available to strawberry growers is not as effective as endosulfan*
- ***Blueberry*** *and* ***Blackcurrant*** *growers are not using endosulfan.*

Ornamentals[5]

3.5.31 Ornamentals are made up of a wide variety of non-edible crops. While it was difficult to identify common practices for this group, Horticulture New Zealand was advised that endosulfan tends to be used as a clean-up spray or when insect pressure is extreme and other products have not, or would not work. Particular target insects identified are western flower thrips, whitefly and mites.

3.5.32 Growers of ornamentals do not have many registered insecticide options, while at the same time they can suffer many problematic pests – in particular western flower thrips, mites (of all kinds) whitefly and aphids. They regard endosulfan is a key backstop product in this area.

Citrus

3.5.33 Horticulture New Zealand reported that endosulfan is the only compound that effectively controls broad mite on lemons and is also a possible control option for citrus whitefly, a new pest of citrus.

3.5.34 Endosulfan is routinely used on citrus crops (1 to 2 sprays per season) for the control of Kelly's citrus thrips, greenhouse thrips, citrus flower moth and broadmite. Broadmite is of particular concern in the production of lemons and there are no other products available that can be used as an alternative. Broadmite control on lemons is an essential use of endosulfan but it also used to some degree for control of thrips and flower moth.

3.5.35 Endosulfan is also currently being reviewed for control of Australian citrus whitefly, a pest that has recently become established in New Zealand. It was first recorded in New Zealand in 2000 but has only become a major commercial problem in the last two years. Controlling whitefly is complicated because of its complex lifecycle. Only certain stages are susceptible to chemical control. Endosulfan has been reported by growers to be effective against whitefly adults but it is the immature stages of the insect that are of greater importance. New Zealand Citrus Growers Inc. is currently funding trial work by HortResearch reviewing a number of products, including endosulfan, against immature stages of whitefly. Results of this work are not yet available, but if whitefly does prove to be susceptible to endosulfan it is likely to be considered as a key control. Because of the relatively new status of this pest, control measures are still in their infancy with mandarin growers appearing to be hardest hit. Gaining long-term control of the citrus whitefly is a major issue facing the citrus industry.

[5] Ornamental growers are not members of Horticulture New Zealand.

Reports on the use of endosulfan on turf in New Zealand provided by New Zealand Sports Turf Institute, PGG Wrightson Turf and the Civil Aviation Authority:

3.5.36 The following information was provided by the New Zealand Sports Turf Institute.[6]

3.5.37 Endosulfan is primarily used within the turf sector for the control of the following pests:

- Earthworms (Allolobophora, Lumbricus sp)
- Porina (*Wiseana sp*)
- Greasy cutworm (Agrotis ipsilon aneituma)
- Sod webworm (various incl *Eudonia sp*).

3.5.38 There are other equally effective pesticide options, other than endosulfan, presently available for controlling Porina, Greasy cutworm and Sod webworm. However in the absence of other equally effective pesticides to endosulfan, this pesticide is required to manage and reduce earthworm numbers on turf and thereby maintain playing quality.

3.5.39 The main turf areas that use endosulfan include:

- Golf courses – greens, tees, fairways rough and other turf areas
- Bowling greens
- Sportsfields
- Stadia
- Cricket outfields
- Racetracks
- Croquet lawns
- Amenity turf areas – lawns
- Aerodromes – runways and associated grassed areas.

3.5.40 In the absence of survey information it is difficult to estimate the actual amount/frequency that endosulfan is used within the turf market. However, NZSTI's best estimate is summarised below in the table below.

[6] The use and importance of endosulfan within the New Zealand turf industry (dated February 2008) and 'Endosulfan Reassessment Report' (dated June 2008).

Table 8: Use of endosulfan for turf management

Turf sector	Estimated % of clubs using endosulfan
Golf	>80% of clubs each year
Bowls	>80% of clubs each year
Councils	20 – 30% of councils each year
Croquet	>60% of clubs each year
Stadia	>80% of stadia each year
Race tracks	30 – 50% of race tracks
Landscaping industry	Negligible

3.5.41 B. Walmsley (PGG Wrightson Turf, pers. comm.) has reported to the Agency that endosulfan is commonly applied to turf at 3 l/ha (1.1 kg a.i./ha) where surface feeding insects such as porina are present and where a light or moderate earthworm problem exists. Application at 6 l/ha (2.1 kg a.i./ha) is used for moderate to severe earthworm problems and where two or more years of control is expected. In all cases, the application is watered in.

3.5.42 New Zealand Civil Aviation Authority has forwarded reports to the Agency from four New Zealand airports indicating endosulfan is used to control earthworms to reduce bird strike and to reduce encroachment of worms onto sealed runways which is deemed a 'Foreign Object Damage' issue. One of the airports reported application at 3.5 l/ha (1.2 kg a.i./ha).

Summary of use patterns evaluated by the Agency for its risk assessment

3.5.43 Given the range of crops and application equipment used to apply endosulfan, the Agency has selected a series of scenarios considered to be representative of all uses for its risk assessment. These are set out in the table below. Exposure of the environment and human health was considered for most of these applications. However, consideration of environmental exposure was not undertaken for glasshouse use since minimal environmental exposure is anticipated to arise. No environmental exposure was considered under back-pack use since the exposure is anticipated to be lower than from vehicle-mounted equipment.

Table 9: Use scenarios evaluated in this application

Scenario	Environment	Human health
Label use: In New Zealand the maximum use rate specified on the label is 0.7 kg a.i./ha. Frequency of use is not specified on the label, the Agency has assumed 4 times per year with an interval of 10 days between applications. The Agency has assumed a high boom with medium droplet size.	Yes	Yes
Label use: application at 0.7 kg/ha to glasshouses using remote trolley sprayers or low-volume misters.	No	Yes
Turf: maximum application rate of 2.1 kg a.i./ha, application once a year and with wetting in following application (B. Walmsley pers. comm.). The Agency assumes a low boom with medium droplet size would be used for such applications.	Yes	Yes
Citrus: maximum application rate of 1.3 kg a.i./ha, twice a year with an application interval of 14 days, using an airblast sprayer (S. Minchin, pers. comm.).	Yes	Yes
Backpack: considered for risks to human health only.	No	Yes

3.5.44 No assessment was made of aerial application or domestic use, since it is understood that neither scenario is relevant to New Zealand.

3.6 Existing controls for endosulfan and endosulfan formulations

3.6.1 The lifecycle and hazardous properties of endosulfan and endosulfan formulations are managed through a variety of controls. These controls are prescribed as part of the approval of these substances under the Act and the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act), and through requirements for resource consents under the Resource Management Act 1991 and are discussed in the following sections.

3.7 Controls applied under the HSNO Act

3.7.1 The controls applicable to endosulfan and endosulfan formulations are given in the following regulations made pursuant to the HSNO Act and the following *New Zealand Gazette* notices. In addition, certain transitional controls may also apply until the end of the relevant transitional period under the *Gazette* notices.

- Hazardous Substances (Classes 1 to 5 Controls) Regulations 2001: Controls to manage (inter alia) the flammability (Class 3) and other properties of a substance.
- Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001: Controls to manage (inter alia) the toxic (Class 6) and ecotoxic (Class 9) properties of a substance, including exposure limits.
- Hazardous Substances (Identification) Regulations 2001: In effect, requirements for labelling, material safety data sheets and workplace information, and advertising.

- Hazardous Substances (Packaging) Regulations 2001: Standards for packaging for specific hazard classes.
- Hazardous Substances (Disposal) Regulations 2001: Information that must be provided in relation to the disposal of specific classes of hazardous substance and packaging.
- Hazardous Substances (Emergency Management) Regulations 2001: Information requirements for the suppliers and people in charge of places. The requirements are set on the basis of the quantities of specific hazard classes on a site, with higher-level requirements for larger quantities and the higher hazard substances.
- Hazardous Substances (Tracking) Regulations 2001: The classes of hazardous substance that have to be under the control of an approved handler, and what records must be kept and for how long.
- Hazardous Substances (Personnel Qualifications) Regulations 2001: The requirements for test certificates for approved handlers and qualifications for enforcement officers. This regulation also specifies the transitional arrangements for existing licence holders.
- Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004 (*New Zealand Gazette* Issue 35, 26 March 2004) (as amended).
- Hazardous Substances (Pesticides) Transfer Notice 2004 (*New Zealand Gazette* Issue 72, 15 June 2004) (as amended).
- Hazardous Substances (Chemicals) Transfer Notice 2006 (*New Zealand Gazette* Issue 72, 28 June 2006).

Hazardous substances regulations

3.7.2 Tables 10, 11 and 12 respectively, summarise the HSNO Act control codes[7] and the controls and additional controls that apply to endosulfan and endosulfan formulations. The HSNO control codes are based on the classifications assigned to the substances (as determined at the time of transfer to the HSNO Act).

3.7.3 The HSNO control codes applicable to endosulfan and endosulfan formulations can be broken down into those controls that manage the hazardous properties of the substances and those that manage the lifecycles of the substances:

- **Hazardous property** controls are designed to manage the hazards arising from a substance's intrinsic hazardous properties, reduce the likelihood of unintended occurrence of the hazard, and limit the adverse effects arising from exposure to the hazard.
- **Lifecycle** controls focus on the lifecycle management of the substances and cover packaging, identification, emergency

7 Control codes are codes ERMA New Zealand has assigned to enable easy cross-referencing to the regulations. These codes are detailed in ERMA New Zealand (2001).

management, disposal, tracking, and the competency of people handling highly hazardous substances.

3.7.4 Where a control has been changed from the default wording this is indicated by a star (*) next to the control code. The detail of this change, including deletion of a control, is listed under Changes to Controls in Table 11.

Table 10: Existing controls for endosulfan and formulations

Substance / HSNO Control		Endosulfan	Emulsifiable concentrate containing 350 g/l endosulfan				
			(Substance A) Endo 350EC	(Substance B) Flavylan 350EC	(Substance C) Thiodan 35EC	(Substance D) Thionex EC350 Insecticide Spray[1]	Thionex Insecticide Solvesso formulation[2]
Class 1 to 5 Controls	F1		✓	✓		✓	
	F2		✓	✓	✓	✓	✓
	F3		✓	✓		✓	
	F4*		✓				
	F5		✓	✓		✓	
	F6		✓	✓	✓	✓	✓
	F11		✓	✓	✓	✓	✓
	F12		✓	✓		✓	
	F14*		✓	✓		✓	
	F16		✓	✓		✓	
Class 6, 8 and 9 controls	T1*	✓	✓	✓	✓	✓	✓
	T2*	✓	✓	✓	✓	✓	✓
	T3	✓	✓	✓	✓	✓	✓
	T4	✓	✓	✓	✓	✓	✓
	T5	✓	✓	✓	✓	✓	✓
	T6*	✓	✓	✓	✓	✓	✓
	T7	✓	✓	✓	✓	✓	✓
	E1*	✓	✓	✓	✓	✓	✓
	E2	✓	✓	✓	✓	✓	✓
	E3	✓	✓	✓	✓	✓	✓
	E5	✓	✓	✓	✓	✓	✓
	E6	✓	✓	✓	✓	✓	✓
	E7*	✓	✓	✓	✓	✓	✓
Packaging controls	P1	✓	✓	✓	✓	✓	✓
	P3	✓	✓	✓	✓	✓	✓
	P5		✓	✓	✓	✓	✓

Substance		Endosulfan	Emulsifiable concentrate containing 350 g/l endosulfan				
			(Substance A) Endo 350EC	(Substance B) Flavylan 350EC	(Substance C) Thiodan 35EC	(Substance D) Thionex EC350 Insecticide Spray[1]	Thionex Insecticide Solvesso formulation[2]
HSNO Control							
	P13	✓	✓	✓	✓	✓	✓
	P14				✓		✓
	P15	✓	✓	✓	✓	✓	✓
	PG2	✓	✓				
	PG3			✓	✓	✓	✓
Disposal controls	D2		✓	✓	✓	✓	✓
	D4	✓	✓	✓	✓	✓	✓
	D5	✓	✓	✓	✓	✓	✓
	D6	✓	✓	✓	✓	✓	✓
	D7	✓	✓	✓	✓	✓	✓
	D8	✓	✓	✓	✓	✓	✓
	AH1	✓	✓	✓	✓	✓	✓
	TR1	✓	✓	✓	✓	✓	✓
Emergency management controls	EM1	✓	✓	✓	✓	✓	✓
	EM2				✓		✓
	EM6	✓	✓	✓	✓	✓	✓
	EM7	✓	✓	✓	✓	✓	✓
	EM8	✓	✓	✓	✓	✓	✓
	EM9		✓	✓	✓	✓	✓
	EM10		✓	✓	✓	✓	✓
	EM11	✓	✓	✓	✓	✓	✓
	EM12*	✓	✓	✓	✓	✓	✓
	EM13	✓	✓	✓	✓	✓	✓
Identification controls	I1	✓	✓	✓	✓	✓	✓
	I2				✓		✓
	I3	✓	✓	✓	✓	✓	✓
	I5		✓	✓	✓	✓	✓
	I8	✓	✓	✓	✓	✓	✓
	I9	✓	✓	✓	✓	✓	✓
	I10				✓		✓
	I11	✓	✓	✓	✓	✓	✓
	I13		✓	✓	✓	✓	✓
	I16	✓	✓	✓	✓	✓	✓

Substance		Endosulfan	Emulsifiable concentrate containing 350 g/l endosulfan				
			(Substance A) Endo 350EC	(Substance B) Flavylan 350EC	(Substance C) Thiodan 35EC	(Substance D) Thionex EC350 Insecticide Spray[1]	Thionex Insecticide Solvesso formulation[2]
HSNO Control							
	I17	✓	✓	✓	✓	✓	✓
	I18	✓	✓	✓	✓	✓	✓
	I19	✓	✓	✓	✓	✓	✓
	I20	✓	✓	✓	✓	✓	✓
	I21	✓	✓	✓	✓	✓	✓
	I22				✓		✓
	I23	✓	✓	✓	✓	✓	✓
	I25		✓	✓	✓	✓	✓
	I28	✓	✓	✓	✓	✓	✓
	I29	✓	✓	✓	✓	✓	✓
	I30	✓	✓	✓	✓	✓	✓

[1] These properties apply to the original formulation containing xylene.

[2] Additional column to show the properties of the Thionex Solvesso formulation.

Table 11: Summary of default controls applicable to endosulfan

Hazardous Substances (Classes 1 to 5 Controls) Regulations 2001		
Code F1	Reg 7	General test certification requirements for hazardous substance locations
Code F2	Reg 8	Restrictions on the carriage of flammable substances on passenger service vehicles
Code F3	Reg 55	General limits on flammable substances
Code F4*	Reg 56	Approved handler/security requirements for certain flammable substances ***Change to default controls*** **Regulation 56 of the Hazardous Substances (Classes 1 to 5 Controls) Regulations 2001** The following regulation is inserted immediately after regulation 56: **56A Exception to approved handler requirement for transportation of packaged pesticides** (1) Regulation 56 is deemed to be complied with if: (a) when this substance is being transported on land— (i) by rail, the person who drives the rail vehicle that is transporting the substance is fully trained in

		accordance with the approved safety system for the time being approved under section 6D of the Transport Services Licensing Act 1989; and (ii) other than by rail, the person who drives, loads, and unloads the vehicle that is transporting the substance has a current dangerous goods endorsement on his or her driver licence; and (iii) in all cases, Land Transport Rule: Dangerous Goods 1999 (Rule 45001) is complied with; or (b) when this substance is being transported by sea, one of the following is complied with: (i) Maritime Rules: Part 24A – Carriage of Cargoes – Dangerous Goods (MR024A): (ii) International Maritime Dangerous Goods Code; or (c) when this substance is being transported by air, Part 92 of the Civil Aviation Rules is complied with. (2) Subclause (1)(a)— (a) does not apply to a tank wagon or a transportable container to which the Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004 applies; but (b) despite paragraph (a), does apply to an intermediate bulk container that complies with chapter 6.5 of the UN Model Regulations. (3) Subclause (1)(c)— (a) applies to pilots, aircrew, and airline ground personnel loading and managing this substance within an aerodrome; but (b) does not apply to— (i) the handling of this substance in any place that is not within an aerodrome; or (ii) the loading and managing of this substance for the purpose of aerial spraying or dropping. (4) In this regulation, UN Model Regulations means the 13th revised edition of the Recommendation on the Transport of Dangerous Goods Model Regulations, published in 2003 by the United Nations.
Code F5	Regs 58, 59	Requirements regarding hazardous atmosphere zones for class 2.1.1, 2.1.2 and 3.1 substances
Code F6	Regs 60–70	Requirements to prevent unintended ignition of class 2.1.1, 2.1.2 and 3.1 substances
Code F11	Reg 76	Segregation of incompatible substances
Code F12	Regs 77	Requirement to establish a hazardous substance locations if flammable substances are present
Code F14*	Reg 81	Test certification requirements for facilities where class 2.1.1, 2.1.2 or 3.1 substances are present

		Change to default controls **Regulation 81 of the Hazardous Substances (Classes 1 to 5 Controls) Regulations 2001** A hazardous substance location does not require a test certificate if— (a) the hazardous substance location is situated on a farm of not less than 4 hectares; and (b) the combined quantity of each class 3.1B or class 3.1C substance and any petrol, aviation gasoline, or racing gasoline stored at the location is less than 2,000 litres; and (c) either— (i) the following requirements are complied with: (A) each substance is stored in 1 or more secure containers, each of which has a capacity of less than 250 litres; and (B) each container complies with regulation 11 and Schedule 2 of the Hazardous Substances (Packaging) Regulations 2001; and (C) each container is— (1) situated not less than 15 metres from any area of high intensity land use or area of regular habitation; and (2) situated either in the open or in a well-ventilated building; and (3) in a compound or located so that any spillage of the substance will not endanger any building, or flow into any stream, lake, or natural water; or (ii) the following requirements are complied with: (A) each substance is stored in an above ground stationary tank that complies with the Stationary Container Controls in Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004, as amended by this Schedule; and (B) each of the above ground stationary tanks is situated— (1) not less than 20 metres from any area of high-intensity land use or area of regular habitation; and (2) 6 metres from any combustible materials; and (3) in a compound or located so that any spillage of the substance will not endanger any building, or flow into any stream, lake, or natural water.
Code F16	Reg 83	Controls on transit depots where flammable substances are present

Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001		
Code T1*	Regs 11 – 27	Limiting exposure to toxic substances through the setting of tolerable exposure limits (TELs) ***Change to default controls*** No TEL is set for this substance at this time.
Code T2*	Regs 29, 30	Controlling exposure in places of work through the setting of Workplace Exposure Standards. **Workplace Exposure Standards** Under regulation 29(2) of the Hazardous Substance (Classes 6, 8, and 9 Controls) Regulations 2001, the Authority adopts as a workplace exposure standard for this substance, and each component of this substance, the value or values specified in the document described in "Workplace Exposure Standards", published by the Occupational Safety and Health Service, Department of Labour, January 2002, ISBN 0-477-03660-0. Also available at www.osh.govt.nz/order/catalogue/pdf/wes2002.pdf.
Code T3	Regs 5(1), 6	Requirements for keeping records of use
Code T4	Reg 7	Requirements for equipment used to handle substances
Code T5	Reg 8	Requirements for protective clothing and equipment
Code T6*	Reg 9	Approved handler/security requirements for certain toxic substances ***Changes to Default Controls*** **Regulation 9 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001** The following regulation is inserted immediately after regulation 9: **9A Exception to approved handler requirement for transportation of packaged pesticides** (1) Regulation 9 is deemed to be complied with if: (a) when this substance is being transported on land— (i) by rail, the person who drives the rail vehicle that is transporting the substance is fully trained in accordance with the approved safety system for the time being approved under section 6D of the Transport Services Licensing Act 1989; and (ii) other than by rail, the person who drives, loads, and unloads the vehicle that is transporting the substance has a current dangerous goods endorsement on his or her driver licence; and (iii) in all cases, Land Transport Rule: Dangerous Goods 1999 (Rule 45001) is complied with; or (b) when this substance is being transported by sea, one of the following is complied with:

		(i) Maritime Rules: Part 24A – Carriage of Cargoes – Dangerous Goods (MR024A): (ii) International Maritime Dangerous Goods Code; or (c) when this substance being transported by air, Part 92 of the Civil Aviation Rules is complied with. (2) Subclause (1)(a)— (a) does not apply to a tank wagon or a transportable container to which the Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004 applies; but (b) despite paragraph (a), does apply to an intermediate bulk container that complies with chapter 6.5 of the UN Model Regulations. (3) Subclause (1)(c)— (a) applies to pilots, aircrew, and airline ground personnel loading and managing this substance within an aerodrome; but (b) does not apply to— (i) the handling of this substance in any place that is not within an aerodrome; or (ii) the loading and managing of this substance for the purpose of aerial spraying or dropping. (4) In this regulation, UN Model Regulations means the 13th revised edition of the Recommendation on the transport of Dangerous Goods Model Regulations, published in 2003 by the United Nations.
Code T7	Reg 10	Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles
Code E1*	Regs 32–45	Limiting exposure to ecotoxic substances through the setting of environmental exposure limits (EELs) ***Changes to Default Controls*** **Regulation 32 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001** Regulation 32 applies as if subclause (1) and (2) were omitted.
Code E2	Regs 46–48	Restrictions on use of substances in application areas
Code E3	Reg 49	Controls relating to protection of terrestrial invertebrates eg beneficial insects
Code E5	Regs 5(2), 6	Requirements for keeping records of use
Code E6	Reg 7	Requirements for equipment used to handle substances
Code E7*	Reg 9	Approved handler/security requirements for certain ecotoxic substances ***Changes to Default Controls for endosulfan*** This regulation applies as if the substance were not a class 9 substance.

		Changes to Default Controls for endosulfan formulations **Regulation 9 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001** The following regulation is inserted immediately after regulation 9: **9A Exception to approved handler requirement for transportation of packaged pesticides** (1) Regulation 9 is deemed to be complied with if: (a) when this substance is being transported on land— (i) by rail, the person who drives the rail vehicle that is transporting the substance is fully trained in accordance with the approved safety system for the time being approved under section 6D of the Transport Services Licensing Act 1989; and (ii) other than by rail, the person who drives, loads, and unloads the vehicle that is transporting the substance has a current dangerous goods endorsement on his or her driver licence; and (iii) in all cases, Land Transport Rule: Dangerous Goods 1999 (Rule 45001) is complied with; or (b) when this substance is being transported by sea, one of the following is complied with: (i) Maritime Rules: Part 24A – Carriage of Cargoes – Dangerous Goods (MR024A): (ii) International Maritime Dangerous Goods Code; or (c) when this substance being transported by air, Part 92 of the Civil Aviation Rules is complied with. (2) Subclause (1)(a)— (a) does not apply to a tank wagon or a transportable container to which the Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004 applies; but (b) despite paragraph (a), does apply to an intermediate bulk container that complies with chapter 6.5 of the UN Model Regulations. (3) Subclause (1)(c)— (a) applies to pilots, aircrew, and airline ground personnel loading and managing this substance within an aerodrome; but (b) does not apply to— (i) the handling of this substance in any place that is not within an aerodrome; or (ii) the loading and managing of this substance for the purpose of aerial spraying or dropping. (4) In this regulation, UN Model Regulations means the 13th revised edition of the Recommendation on the transport of

		Dangerous Goods Model Regulations, published in 2003 by the United Nations.
Hazardous Substances (Packaging) Regulations 2001		
Code P1	Regs 5, 6, 7(1), 8	General packaging requirements
Code P3	Reg 9	Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria
Code P13	Reg 19	Packaging requirements for toxic substances
Code P14	Reg 20	Packaging requirements for corrosive substances
Code P15	Reg 21	Packaging requirements for ecotoxic substances
Code PG2	Schedule 2	Packaging requirements equivalent to UN Packing Group II
Code PG3	Schedule 3	Packaging requirements equivalent to UN Packing Group III

Hazardous Substances (Disposal) Regulations 2001		
Code D2	Reg 6	Disposal requirements for flammable substances
Code D4	Reg 8	Disposal requirements for toxic and corrosive substances
Code D5	Reg 9	Disposal requirements for ecotoxic substances
Code D6	Reg 10	Disposal requirements for packages
Code D7	Regs 11, 12	Information requirements for manufacturers, importers and suppliers, and persons in charge
Code D8	Regs 13, 14	Documentation requirements for manufacturers, importers and suppliers, and persons in charge

Hazardous Substances (Personnel Qualifications) Regulations 2001		
Code AH1	Regs 4 – 6	Approved Handler requirements (including test certificate and qualification requirements)

Hazardous Substances (Tracking) Regulations 2001		
Code TR1	Regs 4(1), 5, 6	General tracking requirements

Hazardous Substances (Emergency Management) Regulations 2001		
Code EM1	Regs 6, 7, 9–11	Level 1 information requirements for suppliers and persons in charge
Code EM2	Reg 8(a)	Information requirements for corrosive substances
Code EM6	Reg 8(e)	Information requirements for toxic substances
Code EM7	Reg 8(f)	Information requirements for ecotoxic substances
Code EM8	Regs 12–16, 18–20	Level 2 information requirements for suppliers and persons in charge
Code EM9	Reg 17	Additional information requirements for flammable and oxidising substances and organic peroxides

Code EM10	Regs 21–24	Fire extinguisher requirements
Code EM11	Regs 25–34	Level 3 emergency management requirements: duties of person in charge, emergency response plans
Code EM12*	Regs 35–41	Level 3 emergency management requirements: secondary containment ***Change to Default Controls*** **Regulations 35-42 of the Hazardous Substances (Emergency Management) Regulations 2001** The following subclauses are added after subclause (3) of regulation 36: (4) For the purposes of this regulation, and regulations 37 to 40, where this substance is contained in pipework that is installed and operated so as to manage any loss of containment in the pipework it— (a) is not to be taken into account in determining whether a place is required to have a secondary containment system; and (b) is not required to be located in a secondary containment system. (5) In this clause, pipework— (a) means piping that— (i) is connected to a stationary container; and (ii) is used to transfer a hazardous substance into or out of the stationary container; and (b) includes a process pipeline or a transfer line.
Code EM13	Reg 42	Level 3 emergency management requirements: signage

Hazardous Substances (Identification) Regulations 2001		
Code I1	Regs 6, 7, 32–35, 36(1) – (7)	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability
Code I2	Reg 8	Priority identifiers for corrosive substances
Code I3	Reg 9	Priority identifiers for ecotoxic substances
Code I5	Reg 11	Priority identifiers for flammable substances
Code I8	Reg 14	Priority identifiers for toxic substances
Code I9	Reg 18	Secondary identifiers for all hazardous substances
Code I10	Reg 19	Secondary identifiers for corrosive substances
Code I11	Reg 20	Secondary identifiers for ecotoxic substances
Code I13	Reg 22	Secondary identifiers for flammable substances
Code I16	Reg 25	Secondary identifiers for toxic substances
Code I17	Reg 26	Use of generic names
Code I18	Reg 27	Requirements for using concentration ranges

Code I19	Regs 29–31	Additional information requirements, including situations where substances are in multiple packaging
Code I20	Reg 36(8)	Durability of information for class 6.1 substances
Code I21	Regs 37–39, 47–50	General documentation requirements
Code I22	Reg 40	Specific documentation requirements for corrosive substances
Code I23	Reg 41	Specific documentation requirements for ecotoxic substances
Code I25	Reg 43	Specific documentation requirements for flammable substances
Code I28	Reg 46	Specific documentation requirements for toxic substances
Code I29	Regs 51, 52	Signage requirements
Code I30	Reg 53	Advertising corrosive and toxic substances

Hazardous Substances (Tank Wagon and Transportable Containers) Regulations 2004

Controls for Stationary Container Systems

These controls are set out in Schedule 8 of the Hazardous Substances (Hazardous Substances (Dangerous Goods and Schedule Toxic Substances) Transfer Notice 2004. The requirements of this schedule are detailed in the Compilation of Hazardous Substances Regulations and Controls (http://www.ermanz.govt.nz/hs/hs-regulations.html).

Change to Default Controls

Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004

Clause 1: This clause applies as if the words "a hazardous substance described in Schedules 1 and 2" in subclause (1) was replaced by:

"this substance".

Clause 100: This clause applies as if subclause (1) was replaced by:

(1) In this Part, existing stationary container system means a stationary container system to which this Schedule applies that, immediately before 1 July 2004,—

(a) was being used to contain this substance; or

(b) was designed to be used to contain this substance, and construction of the stationary container system to that design had commenced.

Controls Relating to the adverse effects of unintended ignition		
Code GN35A*	Schedule 10	Schedule 10 of Gazette Notice Issue 35 - Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004 prescribes additional requirements relating to controlling the adverse effects of unintended ignition of class 2 and 3.1 flammable substances ***Change to Default Controls*** **Schedule 10 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004** Clause 1 This clause applies as if the words "every class 2 and every class 3.1 hazardous substance described in Schedule 1" was replaced by: "this substance". Clause 33 This clause applies as if the words "Subject to subclause (2)" in subclause (1) were omitted. This clause applies as if subclause (2) were omitted.

3.7.5 In addition, the following additional controls were imposed on the substances:

Table 12: Additional HSNO controls applied to endosulfan

Additional controls for endosulfan
1 Prohibition on use of substances (1) No person may use endosulfan for any purpose other than— (a) for research and development; or (b) as an ingredient or component in the manufacture of another substance or product. (2) Despite subclause (1)(a), research and development using endosulfan does not include investigation or experimentation in which the substance is discharged, laid or applied in or to the outdoor environment. **2 Specification of pesticide and veterinary medicine actives** (1) Any person who— (a) manufactures or imports into New Zealand endosulfan, which that person has not previously manufactured or imported on or before 1 July 2006; or (b) had previously manufactured or imported a hazardous substance listed in Table 1 of Schedule 1 on or before 1 July 2006, but that person has since modified the manufacturing process or changed the source of manufacture for that hazardous substance, must provide to the Authority in writing the information required by subclauses (3) and (4). (2) The information required by subclause (1) must be provided— (a) in the case of a substance that is manufactured in New Zealand prior to that substance being sold to another person or used in accordance with clause 1 of Schedule 3; or

(b) in the case of a substance that is imported into New Zealand, prior to that substance being imported; and

(c) in the case of a substance to which subclause (1)(b) applies—

(i) each and every time the manufacturing process or source of manufacture is changed; and

(ii) include equivalent information for the substance that was produced by the manufacturing process before it was modified, or supplied by the previous source of manufacture, if such information has not previously been provided to the Authority.

(3) The information to be provided is—

(a) the name and address of the manufacturer of the substance;

(b) the specification of the substance including either—

(i) the full name, including relevant citation, of the national and/or international standard(s) set by an international scientific or regulatory body recognised by the Authority with which the substance complies, and evidence to support this; or (ii) the manufacturer's specifications including purity of the hazardous substance, isomeric ratio where applicable, maximum impurity content and evidence to support these, including details of analytical methods used. Where the substance is produced at more than one manufacturing site, this information must be provided for each site separately;

(c) the identity of any impurity, its origin, and the nature of its relationship to the active component—

(ii) for endosulfan when the impurity is present at a concentration of 10 g/kg or more;

(d) the identity of any impurity that is known to be of toxicological concern, its origin, and the nature of its relationship to the active component—

(ii) for endosulfan when the impurity is present at a concentration of less than 10 g/kg.

(4) Information on an impurity that is required under subclause (3) must include—

(a) its chemical name;

(b) its Chemical Abstract Service Registry number (if available); and

(c) its maximum concentration in the substance.

Additional controls for endosulfan formulations

Application onto or into water

(1) No hazardous substance containing endosulfan may be applied onto or into water.

(2) In this clause, **water** means water in all its physical forms, whether flowing or not, and whether over or under ground, but does not include water in any form while in a pipe, tank or cistern.

Further explanation of HSNO Act controls

3.7.6 Two of the HSNO controls in particular warrant a more detailed explanation.

Approved handler requirements (control codes T6, E7 and AH1)

3.7.7 The HSNO approvals for endosulfan and endosulfan formulations require these substances to be under the control of an approved handler unless the certain transport requirements for packaged pesticides are met (for example, the substance is transported in accordance with the Land Transport Rule). Approved handler certificates are issued by test certifiers, who are individuals approved by ERMA New Zealand to issue certificates in their area of competency (in this case the management and handling of pesticides).

3.7.8 The purpose of the approved handler certificate is to ensure that a person handling a hazardous substance is trained in how to use or manage the hazardous substance safely and understands the laws and controls (rules) under the Act. To become an approved handler for a substance such as endosulfan, a person must demonstrate:

- knowledge in handling the substance:
  - the hazards of the substance and how to prevent harm to people and damage to the environment;
  - what to do in an emergency;
- practical experience and knowledge of:
  - handling the substance and operating equipment;
  - protective clothing and safety equipment required;
- knowledge of the HSNO legislation:
  - enforcement issues and what the law is trying to achieve;
  - the HSNO Act classifications and regulations that apply to the substance.

Tracking requirements (control code TR1)

3.7.9 Tracking requirements are triggered for endosulfan and endosulfan formulations. Tracking is the recording of what happens to these substances throughout their lifecycle from importation or manufacture in New Zealand, to the point of use and/or disposal. The requirements placed on tracked substances are specified in the Hazardous Substances (Tracking) Regulations 2001.

3.7.10 The purpose of tracking requirements is to ensure appropriately trained and licensed people (ie, approved handlers) are responsible for the hazardous substances throughout their lifecycle in New Zealand. Tracking requirements also ensure that information is available for managing emergencies involving a hazardous substance and enables enforcement agencies to have the ability to track back who has and who should be responsible for the hazardous substance.

3.7.11 Tracking commences at the site of manufacture for a substance that is manufactured in New Zealand. For an imported substance tracking starts at the port. United Nations (UN) or International Civil Aviation Organisation

(ICAO) transport documentation relating to each shipment is considered acceptable records up to the importers premises or person storing the substance on behalf of the importer. The responsibility for keeping records lies with the person in charge[8] of the site where the substance is kept.

3.7.12 The Hazardous Substances (Tracking) Regulations 2001 specify that the following records are kept.

- The identity of the approved handler in control of the substance, including the:
  - person's name, position within the workplace and physical address of the person's place of work;
  - hazard classifications and phases of the lifecycle for which the person is approved;
  - date on which the test certificate lapses or must be reviewed.
- Substance information, including the:
  - unequivocal identification of the tracked substance (eg, the trade name, common name, ERMA New Zealand approval name or number);
  - total amount of tracked substance that is under the control of the approved handler at anyone time (amounts may vary on a daily basis depending on quantities received or dispatched);
  - location of the tracked substance;
  - batch or package number (where required).
- Transfer to another place, including the:
  - unequivocal identification of the substance and the amount transferred;
  - address of the place and the identity of the controlled substance licence holder (including controlled substance licence registration number if available) to whom the substance is being sent;
  - position of the controlled substance licence holder within their organisation;
  - date on which transfer occurred.
- Transport of the tracked substance, including:
  - requirements as per the Land Transport Rules or Maritime or Civil Aviation Rules.
- Disposal or use of the tracked substance, including the:
  - manner of disposal (ie, how the substance was used, consumed or released etc);
  - amount of substance disposed of and the date of disposal;
  - location where the substance was disposed of.

8 The definition of "person in charge" is given in the Hazardous Substances (Classes 1 to 5 Controls) Regulations 2001.

3.8 Non-HSNO Act controls

Agricultural Compounds and Veterinary Medicines Act 1997

3.8.1 Before they can be used, formulations meeting the definition of "agricultural compound" under the Agricultural Compounds and Veterinary Medicines Act 1997, must be approved by the Agricultural Compounds and Veterinary Medicines Group (ACVM Group) of the New Zealand Food Safety Authority. The relevant current registrations for endosulfan formulations are:

- P000039 (11 October 1963) – Thiodan (Bayer New Zealand Ltd), 350 g/L endosulfan.
- P005794 (8 February 2001) – Flavylan 350EC (Adria New Zealand Ltd), 350 g/L endosulfan.
- P07281 (2 June 2005) – Thionex Insecticide (Agronica New Zealand Limited), 350 g/L endosulfan.

3.8.2 The ACVM Group imposes controls (referred to as conditions) on the use of endosulfan formulations under the ACVM Act. The generic conditions applied by the ACVM Group to the substances are detailed in Table 13; no specific conditions have been set by ACVM Group.

Table 13: Agricultural Compounds and Veterinary Medicines Group conditions for endosulfan formulations

ACVM conditions and obligations	Description
1.	The product must be manufactured in accordance with ACVM Standard for Good Manufacturing Practice and to the chemistry and manufacturing specifications provided by the registrant and approved as part of the registration.
2.	In addition to any labelling, advertising or promotion requirements specified in the current registration, labelling, advertising or promotion of the product must comply with the current ACVM - New Zealand Labelling and Advertising Guide for Plant Compounds Requiring Registration in New Zealand.
3.	If the product is used on any food producing plant or on or around any plant not used to produce food: • other than those specified on the current registration; or • in a manner not specified in the current registration, the user must ensure that residues of any substance in the product that may occur in plant material produced from the plants treated, or in animal material produced from grazing or direct feeding of the plants treated to food producing animals, do not exceed the lesser of either: • the specified residue limit in the current New Zealand (Maximum Residue of Agricultural Compounds) Food Standard and any subsequent amendments; or • the default maximum residue limit in the current New Zealand (Maximum Residue of Agricultural Compounds) Food Standard and any subsequent amendments, when a maximum residue limit for that substance has not been specified.[9]

[9] A Maximum Residue Limit (MRL) of 2 mg/kg has been set for endosulfan – see New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2008 (http://www.nzfsa.govt.nz/policy-law/legislation/food-standards/nz-mrl-fs-2008-consolidation.pdf).

ACVM conditions and obligations	Description
4.	Ongoing obligations: The registrant must provide an annual summary of adverse events to the ACVM Group. Adverse events which have serious implications for the continued use of the product must be notified immediately. The registrant must also advise the ACVM Group of any new studies or data that contradicts information previously supplied.
5.	The product must only be sold or imported according to the current registration.[10]

Other requirements

3.8.3 The Resource Management Act 1991 (RMA) regulates discharges to air, ground or water and potentially therefore, conditions may also be imposed on the use of endosulfan formulations under the RMA. These conditions may legally be stricter than controls under the HSNO Act, if that is appropriate for the purposes of the RMA.[11]

3.8.4 In addition, growers and operators using endosulfan will be subject to the requirements of the Health and Safety in Employment Act 1992 which includes the obligation on employers to take all reasonably practicable steps to eliminate, isolate and minimise significant hazards in the workplace.

[10] ACVM advises that the registrations for endosulfan formations P005794 (Flavylan 350EC) and P007281 (Thionex Insecticide) still have this condition, but that ACVM advises intends to delete it as the registrations come up for renewal.

[11] See section 142 of the HSNO Act.

Section Four – Risks, Costs and Benefits

4.1 Identification of the potential risks, costs and benefits of the substances

Risk management context

4.1.1 The Authority decides whether to approve or decline hazardous substances based on the requirements of the Act and the Methodology. The purpose of the Act is to "protect the environment and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms". The Act and the Methodology therefore provide the foundation for the risk management context for the evaluation and review of this application which must be undertaken in accordance with the purpose of the Act.

4.1.2 Section 29 of the Act requires the Authority to consider adverse and positive effects of the substance(s) and to make a decision based on whether or not the positive effects of releasing the substance outweigh the adverse effects of the substance. The relevant adverse and positive effects are those that are associated with the substance.

4.1.3 In particular, in accordance with section 6 of the Act, the following matters have been taken into account in assessing the risks, costs and benefits associated with the use of endosulfan in New Zealand:

- The sustainability of native and valued introduced flora and fauna.
- The intrinsic value of ecosystems.
- Public health.
- The relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga.
- The economic and related benefits to be derived from the use of endosulfan.
- New Zealand's international obligations.

Identification and assessment

4.1.4 The Agency identifies the effects associated with the substance and then undertakes a scoping exercise to determine which effects are potentially significant. Identifying adverse effects requires identifying the sources of effect (eg the hazards), the pathways for exposure, and the areas of impact (outlined below) as well as the likelihood and magnitude of effect. In accordance with clauses 9 and 10 of the Methodology, and sections 5 and 6 of the Act, the adverse and positive effects are characterised in relation to the following areas of impact: the environment, human health and safety,

relationship of Māori to the environment, the market economy, and society and the community.

4.1.5 The second step is to assess the effects that have been identified as being potentially significant. Those effects that are deemed to be not potentially significant are described, but are not assessed. Assessing effects involves combining the magnitude of an effect and the likelihood of it occurring.

Ethical considerations

4.1.6 In reviewing the information provided and identifying and assessing the adverse and positive effects of endosulfan, ethical matters relevant to the use of endosulfan have been taken into account. Guidance is provided by the ERMA New Zealand Ethics Framework Protocol.[12] This framework acknowledges that individuals and communities hold a range of ethical views. It has been developed as a tool to assist all participants in the ERMA New Zealand decision-making process to:

- ask the 'right' questions in order to identify areas where there are ethical matters to be considered; and
- use the answers to these questions to explore whether and how ethical considerations need to be addressed.

4.1.7 The foundation of the framework is a set of ethical principles, supported by procedural standards. The two general principles, which are embodied in the HSNO Act and the Methodology, are:

- respect for the environment; and
- respect for people (including past, present and future generations).

4.1.8 Under these general principles is a set of specific principles:

- concern for animal welfare
- concern for autonomy
- concern for co-operation
- concern for cultural identity/pluralism
- concern for human rights
- concern for human dignity
- concern for justice and equality
- concern for sustainability
- concern for wellbeing/non-harm.

4.1.9 The primary mechanisms for supporting the principles outlined in the framework and for evaluating whether or not they are upheld are the procedural standards of:

- honesty and integrity

[12] December 2005, ER-PR-05-1 12/05.

- transparency and openness
- a sound methodology
- community and expert consultation
- a fair decision-making process.

4.1.10 In preparing this application the Agency has applied the criteria in the procedural standards listed above to its evaluation and review of all the information available to it. In preparing this application, the Agency has been conscious of the concerns expressed by parties who have supplied information to assist in the preparation of this application, and their beliefs that are the basis for these concerns. When ethical dilemmas arise the Agency has described them in terms of the framework.

Analysis of scenarios

4.1.11 Applications for new hazardous substances are made in the context of the existing situation in New Zealand. Therefore, the assessments of adverse and positive effects need to address the additional or incremental effects of the product. In the case of a reassessment the substance is already present in New Zealand so many of its effects are known.

4.1.12 The baseline scenario considered in this assessment is the current situation of endosulfan 350EC being available. The risks involved in this scenario are considered under the use patterns described in Table 9. The alternative scenario in which endosulfan approvals are revoked or modified to restrict use is considered in Section 6 of this application.

4.1.13 These scenarios form the basis for identifying and assessing risks, costs and benefits (adverse and positive effects).

4.2 Risks and costs to human health and the environment

4.2.1 The potential sources of risk to human health and to the environment are tabulated in Table 14.

Table 14: Identification of potential sources of risk

Lifecycle Activity	Associated Source of Risk
Repackaging	An incident during repackaging or labelling
Local transport	Transport or handling incident on roads or during loading/unloading resulting in spillage and subsequent exposure of people or the environment
Storage	Incident during storage, resulting in spillage and subsequent exposure of people and/or the environment
Use	Exposure to users, bystanders and/or the environment during dilution, mixing or use, or through exposure to residues on treated vegetation
Disposal	Disposal of the substance or containers, resulting in release of the substance and subsequent exposure of people and/or the environment

4.2.2 Because of the potential for endosulfan to cause a variety of significant adverse effects on human health, each of the lifecycle activities listed in Table 14 could give rise to potentially significant risks to human health. However, the likelihood of an incident during all stages of the lifecycle except use is considered to be highly improbable. Therefore an assessment of risk to human health has been made only for the use stage of the lifecycle.

4.2.3 As endosulfan is extremely toxic to aquatic life, and very toxic to soil organisms, terrestrial vertebrates and invertebrates, each of the lifecycle activities listed in Table 14 presents potentially significant risks to the environment. However, the likelihood of an incident during all stages of the lifecycle except use is considered to be highly improbable. Therefore an assessment of risk to the environment has been made only for the use stage of the lifecycle.

Reports of adverse effects of endosulfan formulations

4.2.4 One of the grounds for reassessment of the endosulfan products was that reports of adverse effects on human health and the environment constituted new information gathered since endosulfan was first registered. Such reports have been considered again as part of this reassessment application.

New Zealand incident reports

4.2.5 There is a general absence of information on incidents relating to the use of endosulfan in New Zealand.

4.2.6 The New Zealand Food Safety Authority (NZFSA) laid 10 charges against a Northland farmer responsible for the 2006 contamination of meat with the pesticide endosulfan. This represented an off-label use outside of the NZFSA guidance that products used as veterinary medicines, "must confirm, via veterinary advice, that the use is likely to be safe, appropriate, and not cause breaches in residue standards" (ACVM, 2006). This violation lead to a temporary suspension of exports of New Zealand beef to Korea and the responsible farmer being fined $15, 000 plus court costs. Following this incident NZFSA examined whether labelling requirements should be amended to specify that plant protection products should not be used on animals. This has now been implemented for Thionex Insecticide with the label specifying "This product must not be applied on or administered to an animal". Labels for Thiodan and Flavylan 350EC do not contain this warning.

4.2.7 Between 1 July 2002 and 16 July 2007 the National Poisons Centre received eight calls relating to endosulfan. Two calls were simply requests for information. Two were regarding injuries to animals, including seizure in a dog and injuries, ranging from weight loss to death, in baby herons. There were four calls regarding incidents of human exposure. Of the three cases of unintentional exposure, one requested information for treatment but reported no injuries, one reported swelling and a sore nose, and one reported blistered lips, nausea, abdominal pain, sweating and vomiting. No injuries were recorded in the only reported case of an intentional exposure. In all

cases it is not possible to determine the exposure of the affected individual and whether it arose from abuse or normal use.

4.2.8 The Agency notes the lack of incident data which could be due either to a lack of incidents or a lack of reporting or monitoring. B. Walmsley (PGG Wrightson Turf, pers. comm.) has informed the Agency that in 30 years of advising turf managers on the safe and effective use of endosulfan he has not come across any cases of anyone experiencing harm or of environmental damage or fish deaths.

Overseas incident reports

4.2.9 A selection of the many reports of incidents overseas is presented below. Interpretation of the significance of these reports needs to take account of the different application methods and controls that may be applied compared to New Zealand. Some of the incidents will have arisen from practices considered unacceptable in New Zealand. However, in most cases it is impossible to establish such differences from the available reports. The Agency therefore concludes that, although incidents have been reported overseas, it is not possible to determine their relevance to New Zealand.

- Benin: In Borgou province, endosulfan poisoning caused many human deaths during the 1999/2000 cotton season. Official records state that at least 37 people died and a further 36 became seriously ill, although an independent report estimated that nearly 70 people actually lost their lives. Furthermore, farmers in Benin have observed birds and frogs dying following consumption of insects sprayed with endosulfan.
- South Africa: Two children aged 7 and 10 died after coming into contact with a goat treated with endosulfan in February 2003. Endosulfan is sold in South Africa as a vaccination in veterinary medicine (PAN UK, Glin et al., 2006).
- Sudan: In 1988, barrels (previously containing endosulfan) were washed in an irrigation canal and caused massive death of fish; three people died after drinking water from the canal. In 1991, 31 people died after eating seeds treated with endosulfan (PAN UK, Glin et al., 2006).
- Senegal: Investigations in the cotton growing region of Velingara during 2003 and 2004 revealed 157 poisoning incidents, of which 31% involved Callisulfan, an endosulfan-cypermethrin formulation. One death was reported with 23 non-fatalities (PAN UK, Glin et al., 2006).
- Indonesia: In southern Sulawesi endosulfan was the leading cause of pesticide poisoning between 1990 and 1993, with 32 of 153 reported poisoning cases due to endosulfan.
- India: In Kerala, endosulfan has been linked to hundreds of deaths and disorders among cashew nut plantation workers and villagers. In Kasaragod province, where aerial spraying of endosulfan occurred for at least 15 years, high levels of endosulfan residues have been

detected in the blood and breast milk of villagers and cancers and disorders of the reproductive and central nervous systems are common. A survey of only 123 houses found 49 cancer cases, 43 psychiatric cases, 23 epileptics, 9 with congenital abnormalities and 23 with mental retardation.

- Thailand: A survey in five provinces to assess the use of endosulfan for golden apple snail control in paddy fields showed that approximately 94% of farmers used pesticides and that, of those, 60-76% of farmers used endosulfan. Death of fish and other aquatic organisms was reported in every province.
- US: The National Poison Telecommunications Network (NPTN) ranked endosulfan 65th on their list of the top 200 active ingredients for which calls were received from 1984 through 1991, with 53 incidents reported in humans. The EPA Ecological Incident Information System (EIIS) has recorded 91 ecological incidents since 1971 that have been attributed to endosulfan with 96% of these regarding adverse effects to the aquatic environment and 82% involving fish. The National Oceanic and Atmospheric Agency's fish-kill database indicated that endosulfan was responsible for more fish kills in U.S. estuaries and coastal rivers between 1980 and 1989 than all other currently used pesticides at that time. An incident regarding endosulfan runoff from cotton fields killed over 240,000 fish in Alabama in 1995, despite the pesticide reportedly having been applied according to label instructions. The label did not include the instruction not to apply within 300 feet of waterways and some of the fields were slightly within this range; endosulfan was applied to several farms and there was heavy rainfall following some of the applications (PANUPS, 1996).
- Health Canada (2007) report that runoff from endosulfan-treated fields was also strongly implicated in eight incidents of fish-kill on Prince Edward Island in 1999.
- ANZECC (2000) report that fish were killed in lagoons in which the endosulfan concentration was measured 3 days after the kill at 0.15 µg/l, but in another lagoon, small native fish were found when the endosulfan concentration was 0.22 LD_{50} µg/l.
- ANZECC (2000) also report a study that found reductions in populations of five common benthic macroinvertebrate species and a relationship with endosulfan through the use of solvent-filled dialysis bags. However, it was not possible to identify the average or peak concentrations over the sampling period.
- ANZECC (2000) also report a broad chemical and biological monitoring programme across NSW, which showed effects on some macroinvertebrate species including mayflies, but failed to establish a clear link with any particular pesticide.

Risks and costs to society and community

4.2.10 One potentially significant risk to society and community was identified. This relates to increased anxiety in people who are concerned about the continued use of endosulfan, when its use has been either banned or severely restricted in other jurisdictions. This anxiety relates to the reported adverse effects on human health and the environment. This effect is recognised as being real, and it is likely that some level of anxiety will occur if current use patterns are continued. However, the breadth and depth of that anxiety is not known.

4.2.11 Given the lack of information about the size of this effect, it has not been assessed further. It is expected that submissions received during the public consultation period will provide further information that will be considered by the Authority in its evaluation of the application.

Risks and costs to the market economy

4.2.12 There are two potentially significant adverse effects on the market economy that should be considered if the use of endosulfan is to continue in its present form. These are:

- An adverse effect on New Zealand's 'clean green' image resulting from knowledge that New Zealand is continuing to use endosulfan.
- Adverse effects on trade resulting from incidents arising where endosulfan is used incorrectly.

4.2.13 Both of the two adverse effects postulated above would have an adverse effect on New Zealand trade. In 2001 a report commissioned by the Ministry for the Environment (MfE, 2001) concluded that:

- New Zealand's 'clean green' image has value in terms of the way in which particular New Zealand exports benefit from positive perceptions about our environment;
- the 'image' is worth at least hundreds of millions of dollars (per year); and
- New Zealand is relatively "clean and green".

4.2.14 While this report focussed on the impact of products associated with genetically modified organisms on New Zealand's 'clean green' image, the general conclusions are nevertheless relevant.

4.2.15 A study conducted in 2007 (Knight et al, 2007) looking specifically at country of origin and choice of food imports found that country of origin factors appeared largely irrelevant to large food retailers. Consumers do show high willingness to purchase from countries where the country image is an important positive characteristic for the product category and it may therefore, for example, mean that sales of New Zealand apples benefit from image perceptions reinforced by scenery shown in movies. However, a high percentage of New Zealand food exports are unbranded and country of origin is unknown. A further factor is that country of origin labelling can be

negative, with consumers being concerned about 'food miles' and also food quality (having regard to distance travelled).

4.2.16 This is consistent with the point that endosulfan use in onion crops has been declining in recent years because of constraints placed on growers by customers (for example, Tesco in the United Kingdom) and that some markets do not accept onions that have been grown using endosulfan.

4.2.17 Thus, while the use of endosulfan may not directly impact on New Zealand's 'clean green' image as far as individual consumers are concerned it is likely that restrictions may increasingly be placed on products where it is known that endosulfan has been used. At the present time this is at the wholesale buyer level rather than the 'trade ban' level and therefore can be managed at the individual grower level.

4.2.18 Thus, while the use of endosulfan may have an adverse effect on trade, the size of the effect is probably small and able to be managed by growers and industry groups, and it has not been assessed further.

Identification of benefits (positive effects)

4.2.19 The following reports from various user groups identify the value of endosulfan to them.

4.2.20 The Agency identifies that since endosulfan is valued by farmers and horticulturalists its availability will lead to reduced stress in this group of people.

Report on the identification of benefits provided by Makhteshim Chemical Works (MCW)[13]

4.2.21 The following paragraphs were provided by MCW identifying the benefits that accrue from the use of endosulfan formulations.

4.2.22 *Endosulfan belongs to the unique class of "dioxathiepin" chemicals. In New Zealand, it provides a much needed cost effective crop protection tool in a variety of situations. Because of its unique mode of action and chemical makeup, it seems to have an unmatched importance in Integrated Pest Management (IPM) and Resistance Management programs. Because of its low toxicity to honey bees in field situations, it is often a preferred insecticide for use on cross-pollinating crops. Its spectrum of control, particularly against adult phases of the whitefly, aphids, stink and lygus bugs or potato beetles, is superior in many situations to any alternative product. No other insecticidal material exists that has the immediate population knockdown capabilities as endosulfan does against pests such as adult whiteflies, and at the same time is "soft" or selective on beneficial insects, which allows the farmer to use it in IPM. As endosulfan can not be replaced simply by other existing registered products, it takes time to find suitable solutions, which mostly end up of mixtures of two active*

[13] MCW communication dated 29 February 2008.

ingredients. Although new insecticides have been introduced over the last decades, endosulfan is still appreciated by growers and recommended by extension services for the following reasons.

4.2.23 ***Broad spectrum insecticidal/ acaricidal activity -*** *contrary to many new insecticides the biological efficacy of endosulfan allows to control a large spectrum of different pests :*

- *Lepidoptera : (e.g. Helicoverpa spp., Spodoptera spp., Earias, Mamestra, Pieris*
- *Coleoptera : (e.g. Hypothenemus, Leptinotarsa., Anthonomus,, Meligethes)*
- *Heteroptera : (e.g. Nezara , Piezodorus, Myridae)*
- *Homoptera : (e.g. Aphis spp, Bemisia spp)*
- *Mites (Acarina) : (e.g. Eriophydae).*

All these pests are damaging particularly to tomatoes, potatoes, fruits and vegetables as well as ornamentals, which remain key uses for endosulfan in New Zealand. None of the modern insecticides cover the comprehensive pest spectrum like endosulfan. Recent publications have shown that newer products from the neonicitinoids and pyrethroids class are becoming less effective in their control, especially against whiteflies. These new products need to be sprayed more frequently in order to achieve the same results and do not have the selectivity towards beneficial insects. For the replacement of endosulfan it might be necessary to use several active ingredients in alternation or mixtures, as long as resistance management (see below) is not an issue. Further restrictions of its use or even loosing this "unique mode of action" would definitely negatively impact the other product's benefits. Furthermore, endosulfan is the only tool available for certain target pests, especially in view of the minor use crop situation (increasingly important since many organophosphates are being lossed for those uses; e.g. mites in blueberries, cyclamen mites in strawberries, green stink bugs in tomatoes, lygus bug in vegetables). Endosulfan is the only product that works on certain mites in ornamentals.

4.2.24 ***Resistance management -*** *despite the intensive use of endosulfan for more than 50 years all around the world only a few cases of temporary insect resistance have been reported. There are no reports about any significant product failures due to resistance problems. Endosulfan has a unique mode of action different to organophosphates, carbamates, synthetic pyrethroids, neonicotinoids, oxadiazine carboxylate, spinosad and all other classes of insecticides currently available or in development on the market. Furthermore there is no cross resistance in between endosulfan and synthetic pyrethroids, organophosphate, neonicotinoids or other chemical group used in crop protection. The reason for the very limited cases of resistance is related to the multiple sites of action within the GABA receptor*

system, as well as specific interaction with the detoxication (sic) system of pests.

For these reasons, endosulfan is an important tool in Insecticide Resistance Management programs preventing or overcoming resistance against other chemical classes of insecticides. Endosulfan is the ideal product for difficult to control species such as Helicoverpa armigera *and white fly in vegetables and ornamentals, where resistance against other insecticides has occurred. The loss of endosulfan would increase the overuse of other products or combinations of them with the consequence of increasing resistance. Furthermore, due to the lack or restricted use of organophosphates, endosulfan will become even more important within the resistance strategies for the future.*

4.2.25 ***Selectivity on pollinators and beneficials*** *- endosulfan provides high selectivity in favour of beneficial insects and pollinating insects. This allows predators and parasites of important pests to play an economic role in pest control, where honey bees and bumble-bees continue to be a vital part in agriculture/ horticulture through their activities as pollinators. In many countries (see labelling), endosulfan is authorised for use during the flowering/blooming period.*

To optimise the efficacy and selectivity of endosulfan, the product should be sprayed during the early growth stage of the crop (beginning of the spraying campaign). In this case both with the help of the "beneficials" the pest infestation levels will be kept below the economic threshold levels. A specific detoxification system identified in beneficial insects: previous studies performed in Germany have demonstrated that endosulfan is actively detoxified by several species of beneficial insects via the Glutathion-S-Transferase System (GSTs), which conjugates the molecule of endosulfan to the three-peptide glutathion, thus making the molecule unable to bind its target, the GABA receptor. On the other hand, the GST system has demonstrated a lower activity in most of the target pests.

4.2.26 ***Multicrop product due to excellent crop tolerance*** *- since its introduction, endosulfan has shown exceptionally good plant compatibility and tolerance. Reports about phytotoxic effects are extremely scarce and mostly due to uncontrolled tank mixtures with products which were not recommended for mixing with endosulfan.*

4.2.27 ***Cost effectiveness*** *- depending on the pest and crop the dose rates for Thionex Insecticide (350g/l EC) differ from to 1 to 2 litre product/ha. That means product costs for one treatment at farmer level are in the range of 18 to 36NZ$/ha which is by far less compared to product cost for other insecticides with similar spectrum of activity. Alternative products like chlorpyrifos, diazinon, methamidaphos, alpha-cypermethrin, deltamethrin, lambda-cyhalothrin, do not cover all pests. Because endosulfan has a different mode of action it extremely valuable as resistance management tool in prolonging the usefulness of other insecticides such as fipronil,*

imidacloprid and buprofezin. Damage of the crop or alternatively use of several products would be necessary but can not be afforded by the farmer.

Report on the identification of benefits provided by Horticulture New Zealand[14]

4.2.28 The following paragraphs were provided by Horticulture New Zealand as identifying the benefits that accrue from the use of endosulfan formulations.

4.2.29 ***Specific Insect Control –*** *endosulfan is one of the only pesticides available for control of some insects and mites.*

Mite species belonging to the family Tarsonemidae and super family Eriophyoides (gall mites) are not usually controlled by modern miticides developed for control of Tetranychidae. New Zealand Tarsonemidae and gall mites that are controlled by endosulfan include:

- *Broad mite – (Polyphagotarsonemus latus) a pest of many crops, especially greenhouse crops.*
- *Cyclamen mite (Phytonemus pallidus) a pest of strawberries and some flower crops.*
- *Peach bud mite (Tarsonemus waitei) a pest of fruit trees and greenhouse tomatoes.*
- *Red berry mite (Acalitus essigi) a pest of boysenberries and some Rubus species.*
- *Current bud mite (Cecidophyopsis ribis) causes big bud on black currents.*
- *There are also species that affect grapes, pipfruit and citrus. However, to date they do not appear to require specific chemical control measures.*

The white fly and thrip families are another two groups of insects that are particularly difficult to control. Although there are some alternative insecticides available for control of these groups they are limited in number, quick to develop resistance and endosulfan works very well.

4.2.30 ***Broad Spectrum Control/Mode of Action -*** *endosulfan is a broad spectrum insecticide. This ability to control a wide range of damage causing insects is a key reason why the desire is expressed that endosulfan be available for growers to use in the future.*

Being a broad spectrum insecticide also offers tremendous advantages should new strains of insects develop (e.g. the new strain of white fly affecting tomato growers) or when new pest incursions occur (e.g. citrus white fly). These are very real threats to all growers and having a product such as endosulfan available when a situation such as this occurs is vitally important to the horticultural industry.

14 Horticulture New Zealand: Endosulfan use in New Zealand, February 2008.

4.2.31 ***Resistance Management Strategies*** *- endosulfan belongs to the Mode of Action group 2 - GABA-gated chloride channel antagonists, Subgroup A, chemical group cyclodiene organochlorines. Overseas, it has shown some cross-resistance in some pests to fipronil, (which is also in the Mode of Action group 2 - GABA-gated chloride channel antagonists, but is Subgroup B, chemical group fipronil; fipronil does not appear to have a label claim for mite control on plants, although there is one paper claiming control of broad mite - Nick Martin, Crop and Food Research, Personal Communication).*

Endosulfan (2A) provides an alternative Mode of Action group for rotation with other insecticides/miticides. It is included in the following resistance management strategies:

- *Diamond back moth (fipronil (2B) also has a label claim for use on brassicas)*
- *Tomato fruitworm*
- *Thrips, including onion thrips, and western flower thrips, (fipronil (2B) also has a label claim for onion thrips control on onions)*
- *Whitefly*
- *Melon aphid*
- *Green peach aphid. This aphid could be exposed to fipronil (2B) in brassica crops.*
- *Lettuce aphid.*

No resistance to endosulfan has been reported in New Zealand to any of these pests (Nick Martin pers comm.).

Due to new insecticidal chemistry being very selective in mode of action, resistance can develop very quickly. If we are to be good stewards of these new products and prolong their useful life there must be other products to use in rotation with them. Endosulfan as demonstrated above is one such product.

Synthetic Pyrethroid (SP) resistance is widespread in a number of insects and crops. It has been demonstrated that if the use of SP's is stopped for a period of time (length of time will be different for each insect population – but at least several years) this resistance in the insect population can diminish to a level where SP's become effective again. There must be a range of products with different modes of action for growers to choose from if this is to occur. Endosulfan is one such product.

Resistance develops when an insect population is exposed to the same chemistry (or chemistry with the same mode of action) repeatedly. Those insects that survive or escape the insecticide pass on the genetic code or ability that enabled their survival. If only a limited number of insecticides are used this 'selection' for resistance can occur quite quickly. We do not know what resistances will develop in the future – but we can maintain a wide range of chemical options available for growers so that they can

manage this situation, maintain the usefulness of all current chemicals and have the ability to act quickly should a new resistance or pest occur. Endosulfan is a key component of this strategy.

4.2.32 ***Strategic Applications*** *- endosulfan is not widely or routinely used by all growers and all crops, but having it available to use strategically when and if the situation arises is crucial to some.*

Submissions received from growers during pre-notification consultation for this application, acknowledged the use of endosulfan as a backstop application. Endosulfan is often not a first choice chemistry due to the effect on IPM programmes, beneficial insects and bees. However, growers believe that when pest numbers do get out of control endosulfan will be effective. For this reason it is often used strategically, only once or twice a season, when insect pest numbers are very high.

Another strategic use of endosulfan is between crops. This is used primarily by greenhouse and ornamental growers but is not limited to these groups. At the end of a crop cycle before the next crop a strategic one off application of endosulfan may be made to 'clean up' the area making sure that insect pressure is not carried over from one crop to the next. This is an important practice for many growers and with one spray of endosulfan they can reduce their need for insecticides during the subsequent crop life cycle.

Identification of benefits by the turf industry

4.2.33 As discussed above, endosulfan is also used in the turf industry for the control of earthworms, Porina, Greasy cutworm and Sod webworm.

4.2.34 While there are other equally effective pesticide options available for controlling Porina, Greasy cutworm and Sod webworm, there are none available for earthworms. Endosulfan is used to manage and reduce earthworm numbers on turf and thereby maintain playing quality.

4.2.35 In a report received from the New Zealand Sports Turf Institute,[15] the Institute advised that the New Zealand turf industry wishes to retain the use of endosulfan as it provides a cost-effective control of earthworms and thus assists in providing quality playing areas for sports users. NZSTI identified the following aspects of the problem posed by earthworms in New Zealand:

- New Zealand's mild maritime climate ensures adequate soil moisture enabling earthworms to thrive.
- New Zealand soils have "significant" organic matter which helps support a large earthworm population.
- New Zealand's predominant earthworm species have a surface casting habit.

15 Endosulfan Reassessment Report dated June 2008.

- New Zealand's soils are generally poorly drained silt and clays which can be further compromised by the activities of surface casting worms.
- A large part of New Zealand's sporting calendar occurs during winter/spring when soil conditions are wet. It is as this time that they are most vulnerable to compaction and surface sealing.

4.2.34 NZSTI advised that similar issues apply in Britain, where organo chloride products for control of earthworms were removed from the market in 1992, thus requiring reliance on more expensive, less effective alternatives such as carbendazim. This has apparently led to a reduction in turf quality in Britain. NZSTI wishes to avoid these problems and the additional costs associated with reduced longevity of sports turf assets and/or in mitigating or addressing earthworm problems without the ability to use endosulfan. NZSTI also pointed out the "social cost" of sportspeople not being able to play due to unacceptable conditions/venue closure.

Summary of benefits identified by users in discussions during the development of this application

4.2.36 The following table summarises the potential benefits from the use of endosulphan identified by users, grouped into effects on the environment, effects on human health and safety, effects on society and community and effects on the market economy.

Table 15: Summary of benefits from the use of endosulfan

Area of effect	Description	Accrues to ...
Benefits to the Environment	A lack of adverse effects on non-target species has been claimed by some parties but not others (including honey bees)	Horticulturalists
Benefits to Human Health and Safety	Reduced risks to people from ability to control earthworms and reduce castings which can cause injury through uneven surfaces	Individuals (ranging from sport players to vehicle occupants)
	Reduced risk to air travellers from reduction in risk of birdstrike	Air travellers, airport authorities
Benefits to Society and Community	Reduced stress to horticulturalists and farmers from knowing that there is a good backstop product available	Horticulturalists
	Reduced concern on part of managers of sports facilities and sports participants	Sports managers and participants
	Reduced risk of playing areas being closed/enhanced turf quality for sports	Turf Managers and participants
Benefits to the Market Economy	Reduced cost of control of insects in the agricultural and horticultural sectors	Horticulturalists
	Reduced cost of control of earthworms (range of possible costs) and less need to resurface areas	Turf Managers
	Reduced cost of control of earthworms at airports	Airport authorities
	Reduced cost of development and testing of new products as pests don't develop resistance	Horticulturalists
	Ability to be able to 'salvage' crops	Horticulturalists

4.3 Assessment of potentially significant risks, costs and benefits

4.3.1 The potentially significant adverse effects, costs and benefits arising from the events identified in Table 14 are considered with respect to:

- The safeguarding of the life-supporting capacity of air, water, soil and ecosystems.
- The maintenance and enhancement of people and communities to provide for their own economic, social, and cultural wellbeing and for the reasonable foreseeable needs of future generations.

4.3.2 The analysis during the use phase of the lifecycle used modelling to estimate exposure. For all other stages of the lifecycle, the assessment was qualitative and determined that the likelihood of an incident was highly improbable and therefore no further analysis was performed.

Assessment of environmental risks

4.3.3 An estimation of environmental risks has been made on the basis of available information on the use of endosulfan using standard modelling tools to estimate exposure concentrations in combination with the data on the ecotoxicity of the substance and its main metabolite endosulfan sulphate.

4.3.4 For Class 9 substances, irrespective of the intrinsic hazard classification, the ecological risk can be assessed for a substance or its components by calculating a risk quotient (RQ) based on measured or estimated exposure concentrations. Estimated exposure concentrations (EEC) are calculated taking into account use scenarios (including spray drift, application rates and frequencies), and the fate of the product including half-lives of the component(s) in soil and water. Dividing an EEC by the LC_{50} or EC_{50} generates an acute RQ whilst dividing the EEC by the NOEC generates a chronic RQ as follows:

$$\text{Acute RQ} = \frac{\text{EEC}}{LC_{50} \text{ or } EC_{50}} \qquad \text{Chronic RQ} = \frac{\text{EEC}}{\text{NOEC}}$$

4.3.5 If the RQ exceeds a predefined level of concern (see below), it may be appropriate to refine the risk assessment or apply controls to ensure that appropriate matters are taken into account to minimise off-site movement of the substance. Conversely, if a worst-case scenario is used, and the level of concern is not exceeded, then in terms of the environment, there is a presumption of low risk which is able to be adequately managed by existing controls.

4.3.6 Levels of concern (LOC) developed by the USEPA (Urban & Cook, 1986), and adopted by ERMA New Zealand, to determine whether a substance poses an environmental risk are shown in Table 16.

Table 16: Levels of concern in environmental risk assessment

	Level of Concern (LOC)	Presumption
Aquatic (fish, invertebrates)		
Acute RQ	≥0.5	High acute risk
	0.1–0.5	Risk can be mitigated through restricted use
	<0.1	Low acute risk
Chronic RQ	≥1	High chronic risk
Plants (aquatic and terrestrial)		
Acute RQ	≥1	High acute risk
Mammal and birds		
Acute dietary or oral RQ	≥0.5	High acute risk
Chronic RQ	≥1	High chronic risk

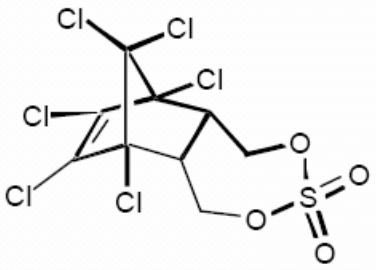
Ecotoxicity

4.3.7 There is a large body of ecotoxicity data on endosulfan and its metabolites. This has been extensively reviewed by other bodies (ANZECC 2000; GFEA-U, 2007; USEPA, 2002, 2007c; APVMA, 1998; Health Canada 2007). In most cases, the ecotoxicity data used by the Agency for risk assessment have been taken from these reviews, particularly ANZECC (2000) and USEPA (2002) and have not been further reviewed for data quality. The ecotoxicity values used for risk assessment are shown in the sections relating to the different compartments below.

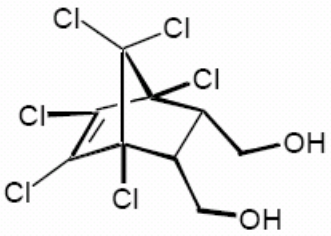
Environmental fate

4.3.8 Exposure is a product of use patterns and fate parameters. Fate in the different environmental compartments is discussed below. Environmental fate has been discussed extensively in other reviews of endosulfan (USEPA, 2002; APVMA, 1998). Only a summary is presented here.

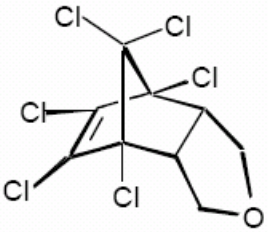
4.3.9 The degradation products of endosulfan in the environment, as shown in APVMA (1998) are illustrated below. The formation of the various metabolites in the different environmental compartments is described under the relevant sections below.



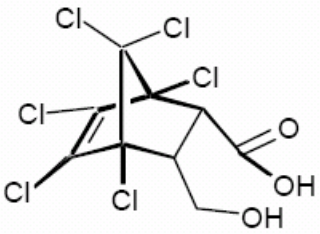
endosulfan sulfate



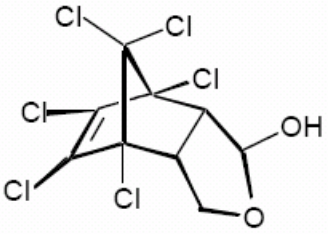
endosulfan diol



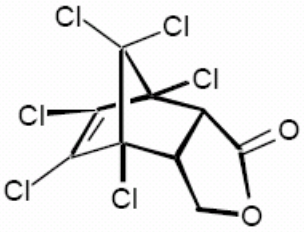
endosulfan ether



endosulfan hydroxycarboxylic acid



endosulfan hydroxyether



endosulfan lactone

Fate in water

4.3.10 Endosulfan is photolytically stable in water, apart from some photoisomerisation of the β- to the α-isomer (APVMA, 1998).

4.3.11 Hydrolysis of endosulfan is pH dependent, half-lives at pH 5.5 and 8.0 at 22 °C of 150 and 1 day respectively (CalEPA, 2007). At pH7, the half-life of α-endosulfan is estimated to be 19 days and this has been used in the USEPA (2007c) modelling of environmental fate.[16] Endosulfan diol is the only product detected during endosulfan hydrolysis studies (APVMA, 1998).

4.3.12 APVMA (1998) report that total endosulfan residues in a pH7.2-7.9 river water/sediment system (98% sand, 0.5% organic carbon, 22°C, incubated in

[16] Note that USEPA (2002) report 19 days to be the half-life of β-endosulfan (11 days for α-endosulfan) and this appears more likely given that the α-isomer degrades more quickly than the β-isomer (Guerin & Kennedy, 1992).

the dark) had a half-life of about 2 weeks. Degradation was initially by biological oxidation to endosulfan sulphate. Endosulfan sulphate amounted to about 20% of applied endosulfan after 1 day, largely in the water phase, increasing to 30-50% after 8 days when it was split approximately equally between the water and sediment, then decreasing to 10% after 7 weeks (the final sampling), when it was associated primarily with the sediment. Hydrolysis appeared to follow the initial biological oxidation, with endosulfan hydroxycarboxylic acid increasing from low levels at Day 4 to 30% at Day 16, before reducing to 10% after 7 weeks. The hydroxycarboxylic acid was associated with the water phase. Non-extractable sediment residues increased to about 20-27% after 7 weeks. Less than 1% of the applied endosulfan was recovered as CO_2 indicating slow mineralisation. APVMA (1998) state that this is the one study for which the results can be considered reliable. Ramanarayanan & Allen (1999a) analyse what appears to be the same study and derive a dissipation half-life of 21 days. Ramanarayanan et al (1999) derive a half-life of 19 days based on Ramanarayanan & Allen (1999a) and use this in their modelling of endosulfan fate. The Agency used a dissipation half-life value of 19 days in the aquatic exposure modelling since it is for total endosulfan residues from a study reported to be reliable. It is unclear how Ramanarayanan et al (1999) made the conversion from 21 days to 19 days, but in practice the difference has very little impact on estimated environmental concentrations as modelled by the Agency.

4.3.13 USEPA (2007c) use an aquatic metabolism half-life of 2671 days, this being twice the soil metabolism half-life, but the hydrolysis half-life of 19 days is also inputted to their modelling.

4.3.14 The high K_{oc} values of endosulfan, 10600 and 13600 L/kg for the α- and β-isomers (USEPA, 2002) indicate that it will tend to sorb to solids, although as described above, rapid biotic oxidation to endosulfan sulphate occurs and this will remain in the water column for several weeks.

Fate in soil

4.3.15 Endosulfan is photolytically stable on soil and plant surfaces. Endosulfan sulphate is found on plant surfaces but is thought to occur from thermal rather than photolytic degradation (APVMA, 1998).

4.3.16 Laboratory studies of soil microorganisms in nutrient solutions have shown that fungi tend to degrade endosulfan to endosulfan sulphate, while bacteria degrade it to endosulfan diol. Endosulfan diol has been shown to degrade further via the ether to hydroxyether and then to the lactone (APVMA, 1998). Soil degradation studies have shown endosulfan sulphate to be the main metabolite. For example, in one study using soils from several sites, endosulfan sulphate reached 34-77% of applied endosulfan after a year, with the diol and lactone generally reaching <2%.

4.3.17 Endosulfan sulphate degrades more slowly than endosulfan. In one study using a soil at pH7.1, 5.1% organic matter, first half-lives of 23, 58 and 100-150 days were derived for α- and β-isomers and endosulfan sulphate

respectively (APVMA, 1998). Half-lives for α- and β-isomers, in acidic to neutral aerobic soils range from 1-3 months and 3-9 months for the α- and β-isomers (USEPA, 2002). These figures are assumed to be for degradation rather than dissipation. APVMA give degradation half-lives of 80-128 days for the α- and β-isomers and of 288 days to 2241 days for the combined α- and β-isomers and the sulphate in 5 soils (sandy loam, loamy sand and silty loam) with mineralisation ranging from 0.4-9.7% after a year. It is noted that long-term laboratory degradation studies may be affected by the difficulty of maintaining viable microbial communities over long periods in the laboratory.

4.3.18 Under field conditions, dissipation including by degradation, transport and uptake, suggests half-lives of weeks to months (USEPA, 2002). The combined half-life (assumed to be a dissipation half-life) of parent and sulphate is estimated to be 9 months to 6 years (USEPA, 2002).

4.3.19 Baedelt et al (1992) looked at field dissipation in two soils, a silty loam and a sandy, silty loam and observed average half-lives of 27 days for parent endosulfan, 175 days for parent plus sulphate metabolite.

4.3.20 Kennedy et al (2001) describe a 2-phase dissipation process, with half-lives in foliage and soil of 1.6 and 7.1 days for the first phase, 9.5 and 82 days for the second.

4.3.21 The soil half-life used in exposure modelling by the USEPA (2007c) is 1336 days, this being the upper 90% confidence limit of endosulfan and its metabolites in soil metabolism studies.

4.3.22 Given the equivalent toxicity of endosulfan and endosulfan sulphate, the Agency has used half-lives reflecting the degradation of parent and metabolite in estimating environmental concentrations. A value of 1336 days has been used in the modelling in accordance with USEPA (2007c).

4.3.23 Endosulfan α- and β-isomers have average K_{oc} values of 10600 and 13600 (USEPA, 2002) indicating strong sorption. Endosulfan sulphate has a similar K_{oc} to endosulfan, 7300-11400, but endosulfan diol sorbs less strongly 990-1200 (APVMA, 1998). Strong sorption does not preclude run-off of endosulfan bound to soil particles and this may be an important route of water body contamination. Leaching studies confirm these high K_{oc} values with practically no endosulfan or its metabolites being found in the leachate (APVMA, 1998).

Fate in air

4.3.24 Endosulfan has a vapour pressure of $1.7E^{-3}$ Pa, (GFEA-U, 2007) and Henry's Law constant variably measured at 0.7-12.9 (α-isomer) and 0.04-2.12 (β-isomer) $Pa.m^{-3}.mol^{-1}$ (GFEA-U, 2007). Wind tunnel experiments (21-22°C, 50% humidity, air speed 1 m/second) have given half-lives of technical endosulfan from foliage and soil of one and three days respectively (APVMA 1998). Endosulfan sulphate has a lower tendency to volatilise (APMA, 1998). Aerial transport of endosulfan sorbed to dust may

be another transport route (USEPA, 2002). Deposition from air to water may be expected given the high water-air partition coefficients, 700 for the α-isomer, 14000 for the β-isomer, 56000 for endosulfan sulphate, all at 25°C (APVMA, 1998).

4.3.25 A half-life of 3.9 to 8.4 days has been calculated for reaction of endosulfan with hydroxyl radicals in air based using a hydroxyl radical concentration of 8.3-18x105 per mL (APVMA, 1998).

4.3.26 Raupach et al (2001) describe a model for the dissipation of endosulfan and its metabolites from cotton fields. The model stresses that spray drift and volatilisation from plants and soil will give rise to airborne endosulfan that will provide a 'steady drizzle' onto non-target areas, while run-off from heavy rain events will give rise to peak inputs to adjacent non-target areas.

4.3.27 APVMA (1998) state that endosulfan will be a regional rather than a global air pollutant as its volatility is too low to enable global distribution, although it is noted that endosulfan has been detected in the Canadian Arctic snowpack, suggesting widespread distribution. Shen et al (2005) quote three models predicting that characteristic travel distances of α-endosulfan will be of the order of 658, 665 and 3520 km.

Bioconcentration/bioaccumulation/biomagnification

4.3.28 The log Kow of the α-isomer, β-isomer and endosulfan sulphate are 3.55-4.74, 3.62-4.78 and 3.66 respectively (USEPA, 2007c), suggesting a potential for bioconcentration.

4.3.29 USEPA (2007c) provide a preliminary assessment of bioconcentration factors (BCF) from laboratory studies. The data from the best quality studies have BCF in the range of 1000-3000 for fish and 20-600 for invertebrates. These BCF are from studies that analysed α-isomer, β-isomer and endosulfan sulphate.

4.3.30 USEPA (2007c) note that depuration of endosulfan and endosulfan sulphate by fish appears to be relatively rapid with clearance half-lives ranging from 2-6 days, although, assuming first-order kinetics, this is somewhat at odds with studies that show steady-state was not reached in 3-4 weeks. The assumption of first-order kinetics may be an over-simplification. Studies of depuration in invertebrates suggests a range of clearance half-lives of 1.5 days to 2 weeks, although these studies do have limitations.

4.3.31 No bioaccumulation factors (BAF, exposure through food as well as by respiration) have been measured for fish, but for the invertebrates *Crassostrea virginica* and *Daphnia magna*, they are about 600. In the absence of measured data, the USEPA modelled bioaccumulation using the food web model of Arnot & Gobas (2004). The model estimates correlate well with measured values where they are available (BCF for fish and invertebrates and BAF for invertebrates). Predicted BAF for fish, for which there are no measured values, are up to 1800 for piscivorous fish.

4.3.32 The USEPA modelling also looked at biomagnification factors (BMF) that express concentrations in an organism compared to those in its diet on a lipid-normalised basis. All aquatic BMF are estimated to be less than one, except for piscivorous fish (1.38), indicating that biomagnification is unlikely to occur in aquatic food webs.

4.3.33 Kelly et al (2007) predict that for substances like endosulfan with a tendency to partition from air into organisms as given by a high octanol air partition coefficient (log KOA ≥6 and log Kow between 2-5), biomagnification in terrestrial (air-respiring) organisms may be greater than for aquatic ones. This is presumed to be due to their greater ability to assimilate food from their diet due to differences in digestive tract physiology and temperature and their lower ability to eliminate the chemicals by respiration. The predictions for β-endosulfan are for BMF values <1 for water-respiring organisms, 10 for seabirds, 22 for marine mammals. USEPA (2007c) compare these predictions to measured residue data from beluga (whales) and ringed seals. The measured data indicate BMF for male and female beluga of 7 and 3, while for male and female ringed seals the BMF are 2 and 1. USEPA (2007c) stress the preliminary nature of this comparison, given the paucity of residue data and assumptions made about the diet of beluga and ringed seal. Mackay & Arnold (2005) also analyse fish to mammal BMF based on measured residues in Arctic fauna and stress the variability around their estimate for α-endosulfan (10.2 ± 16.4).

4.3.34 The above analysis for Arctic wildlife indicates that biomagnification resulting from global distribution of endosulfan may occur. The model of Kelly et al (2007) appears to confirm the residues in biota of many high KOA, medium-to-high Kow substances, but the data are lacking to confirm its suitability for endosulfan. Furthermore, the exposure of seabirds or marine mammals will be largely determined by global emissions of endosulfan, the control of which falls outside this risk assessment. The food web of Arnot and Gobas (2004) is used to analyse the risk to waterbirds (see below).

Use Patterns

4.3.35 Use patterns are discussed in detail in Section 3 above. In the environmental risk assessment risks from the following uses are evaluated:

- Label use: 0.7 kg a.i./ha, application 4 times/year using high boom.
- Turf use: 2.1 kg a.i./ha, application once a year with a low boom and with wetting in following application
- Citrus use: 1.3 kg a.i./ha, twice a year with an application interval of 14 days, using an airblast sprayer.

Aquatic risk assessment

Aquatic exposure – monitoring

4.3.36 There are many literature reports of environmental monitoring for endosulfan from different parts of the world. The Agency has reviewed some of these studies, selected to include all New Zealand monitoring and a variety of environmental media in other parts of the world (Appendix C) and makes the following observations:

- There appear to be only two published reports of monitoring in New Zealand, and these relate to six bark samples taken at three sites (Simonich & Hites, 1995, 1997). There is no information in these reports concerning the selection of sampling sites.
- It is possible that other bodies, such as Regional Councils, may hold more information from environmental monitoring. Regional Councils were approached for information as part of the 'pre-notification' consultation undertaken earlier this year, but such monitoring data was not provided.
- Monitoring of remote regions relevant to New Zealand showed endosulfan metabolites in Antarctic ice, location of sampling unreported (Deger et al, 2003). Endosulfan has also been detected in the blubber of Antarctic wildlife (Miranda-Filho et al, 2007). Monitoring of overseas remote regions (see for example, Carrera et al, 2002; Brun et al, 2007) would suggest that New Zealand's remote regions would receive endosulfan originating from New Zealand's use of endosulfan and from global long-range transport of endosulfan. High regional cropland intensity (within 150 km of site), assumed to be associated with high use of endosulfan, has been correlated with higher residues in remote regions such as the Rocky Mountain National Park (Usenko et al, 2007). Insufficient information is available to the Agency to enable it to quantify concentrations in New Zealand's remote regions but New Zealand's remoteness will limit regional (international) input and domestic use of 5-7 tonnes a.i./year, is very low compared to global use (decreasing from a 2001 peak of about 13000 tonnes (Mackay & Arnold, 2005)). Concentrations in remote regions of New Zealand are therefore unlikely to exceed those seen in remote areas elsewhere. It is noted that Antarctic regions have lower concentrations of many organochlorines and PCBs than Arctic regions (Miranda-Filho et al, 2007).
- With few exceptions, the overseas reports examined by the Agency have not enabled concentrations monitored to be related to local use of endosulfan, due to an absence of information on use in relation to the monitoring sites. It is for this reason that the Agency has not reviewed more of the available overseas monitoring literature. One notable exception is the study of Kennedy et al (2001) of endosulfan application to cotton in Australia. While the crop and environment are different to the New Zealand use scenario this study does demonstrate aspects of the fate of endosulfan in the environment. This was a 3-year, mass-balance study of endosulfan fate from two fields to which

endosulfan was applied at 0.75 kg a.i./ha, 3 or 4 times a year. The soils were grey cracking clays (vertosols) which are strong, friable and prone to forming large deep cracks from the surface when drying. The soils were 60-65% clay, 17-25% silt, 13-16% sand and about 1% organic carbon. Some of the soils had patches of red soils with lower clay content and higher sand content. pH was 7.7-8.7. The analysis showed that: up to 70% of the endosulfan volatilised in the first few days after application; only 2% of the endosulfan dissipated through run-off (even for this irrigated crop); 25-30% was degraded either by the crop itself or in soil; 1% remained in the soil, largely as endosulfan sulphate, at the start of the succeeding year. The authors stress the sensitivity of the mass-balance to heavy rainfall in the days succeeding application and to interception of the spray by the crop, with applications early in the season leading to higher soil residues and potential for run-off losses.

- Some of the monitoring has analysed for endosulfan sulphate as well as α- and β-endosulfan but much has not. Given the similarity in toxicity between the sulphate and parent isomers and the greater persistence of the sulphate, this is a significant shortcoming of those studies that do not include the sulphate.
- Given the comparatively small number of studies examined by the Agency, and the variety of media and locations sampled, it is not possible to summarise concentrations of endosulfan monitored in environmental media.
- APVMA (2005) reports on the effectiveness of measures taken to reduce endosulfan contamination of waterways in cotton growing areas, as determined by monitoring. The percentage of water samples with endosulfan detected remained fairly constant at around 50% throughout the 1990's. However, after 1999, when the measures were introduced, the percentage of samples with detectable residues dropped, to around 5% in 2001/2 the most recent year for which data were reported. This drop was attributed to additional control measures, but it is noted that endosulfan usage also dropped from about 2.6 kg a.i./ha in 1993/1994, to 0.5-1.0 kg a.i./ha in 2002/2003 (on non-GM cotton) and therefore the direct effects of the measures taken is difficult to evaluate.

4.3.37 The Agency concludes that:

- In evaluating monitoring reports, it is necessary to consider local (within a few km), regional (100's of kms) and global depositions of endosulfan.
- Extensive overseas monitoring has demonstrated volatilisation and regional and global distribution of endosulfan, but, by virtue of the way the information has been reported, this cannot be used to relate local use to local environmental concentrations and hence risk.
- Analyses for endosulfan have not been reported from remote regions of New Zealand (including New Zealand's sub-Antarctic islands, marine areas, mountain areas), although reports from similar

environments overseas would suggest low concentrations would be expected.

- New Zealand's use of endosulfan will contribute to global emissions and global contamination of remote areas. The Agency lacks the tools to manage such long-range transport but it is being addressed at the international level, in particular by the United Nations Environment Programme Persistent Organic Pollutants Review Committee.

4.3.38 Consideration of environmental exposure in this risk assessment has focused on local scale emissions. As the Agency is unaware of local monitoring, its local risk assessment is based on modelling estimated environmental concentrations.

Aquatic Exposure – modelling

4.3.39 Environmental exposure has been estimated by the Agency using the GENEEC2 model (USEPA, 2001). More refined assessment has been included in overseas reviews and provided by Makhteshim (MCW). However, no such higher tier modelling has yet been performed to reflect New Zealand conditions and use patterns, although MCW has indicated that it may be able to provide this data during the period available for public submissions.

GENEEC2 modelling of New Zealand endosulfan use

4.3.40 The Agency used the GENEEC2 surface water exposure model (USEPA, 2001) to estimate the EEC of endosulfan in surface waters which could arise as a result of spray drift and surface run-off from the use of endosulfan formulations in New Zealand.

4.3.41 Parameters used in the GENEEC modelling of environmental exposure are listed below. Use rates represent the highest rate for recommended uses. Half-lives relate to the degradation of parent and the sulphate metabolite.

Table 17: Aquatic risk assessment – GENEEC2 input parameters

Scenario 1 – Use according to label

Model Parameter		Reference
Application rate	0.7 kg a.i./ha	Label for all products sold in New Zealand
Application frequency	4 times per season	Max rate 200mL/100L or 2L/ha (equivalent to 0.7 kg a.i/ha), the maximum number of applications per season is not given, therefore a conservative estimate of 4 applications per season has been used for modelling, minimum application interval 10 days.
Application interval	10 days	
Application method	High boom, medium droplet size	
Pesticide wetted in?	No	

Scenario 2 – 'off-label' turf use

Model Parameter		Reference
Application rate	2.1 kg a.i./ha (maximum rate)	B. Walmsley (pers.comm.)
Application frequency	1 time a season	
Application method	Low boom, medium droplet size	
Pesticide wetted in?	Yes	

Scenario 3 – 'off-label' citrus use

Model Parameter		Reference
Application rate	1.3 kg a.i./ha (maximum rate)	S. Minchin (pers.comm.)
Application frequency	2 times a season	
Application interval	14	
Application method	Airblast, orchard	
Pesticide wetted in?	No	

All scenarios

Model Parameter		Reference
K_{oc}	10600	USEPA (2007c) α-isomer
Aerobic soil DT_{50}[1]	1336 days	USEPA (2007c)
'No spray' zone	None	
Water solubility	0.33 ppm	APVMA (1998a)
Aerobic aquatic DT_{50}[1]	19 days	Ramanarayanan et al (1999)
Aqueous photolysis DT_{50}	Stable	APVMA (1998)

[1] half-life of endosulfan and endosulfan sulphate

4.3.42 MCW has suggested that the Agency should use a shorter half-life in soil based on Baedelt et al (1992) who report on the results of field trials in which the concentration of endosulfan sulphate reached a peak after 91 days and had decreased to 50% of this concentration after a further 175 days. Irrespective of the validity of an assessment based on one field trial at one site (the trial involved two sites, but the data were too variable at one of them to determine a DT_{50}), the GENEEC model is little affected by half-life of this duration. A half-life of 266 days gives EEC values very similar to those derived with a half-life of 1336 days.

4.3.43 The output from the GENEEC modelling is shown in Tables 18 and 19.

Table 18: Aquatic exposure as estimated by GENEEC2 model

Scenario 1 –Use at label rate

```
   RUN No.  1 FOR Endosulfan     ON  Label    * INPUT VALUES *
 ---------------------------------------------------------------------
 RATE (#/AC)  No.APPS &  SOIL  SOLUBIL  APPL TYPE NO-SPRAY INCORP
   ONE(MULT)   INTERVAL   Koc  (PPB )   (%DRIFT)  (FT)    (IN)
 ---------------------------------------------------------------------
 .623(  2.474)  4  10  10600.0  330.0  GRHIME(  1.2)    .0   .0


 FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)
 ---------------------------------------------------------------------
 METABOLIC  DAYS UNTIL  HYDROLYSIS  PHOTOLYSIS  METABOLIC  COMBINED
  (FIELD)  RAIN/RUNOFF  (POND)    (POND-EFF)   (POND)    (POND)
 ---------------------------------------------------------------------
 1336.00      2       N/A     .00-    .00   19.00    19.00


 GENERIC EECs (IN MICROGRAMS/LITER (PPB))    Version 2.0 Aug 1, 2001
 ---------------------------------------------------------------------
   PEAK    MAX 4 DAY    MAX 21 DAY   MAX 60 DAY   MAX 90 DAY
   GEEC    AVG GEEC     AVG GEEC    AVG GEEC    AVG GEEC
 ---------------------------------------------------------------------
   13.23     12.42       8.85       4.79       3.39
```

Scenario 2 –Use on turf

```
 RUN No.  2 FOR Endosulfan     ON  Turf       * INPUT VALUES *
 ---------------------------------------------------------------------
 RATE (#/AC)  No.APPS &  SOIL  SOLUBIL  APPL TYPE NO-SPRAY INCORP
  ONE(MULT)   INTERVAL   Koc  (PPB )   (%DRIFT)  (FT)    (IN)
 ---------------------------------------------------------------------
1.870(  1.870)  1  1  10600.0  330.0  GRLOME(  .8)    .0   .0


 FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)
 ---------------------------------------------------------------------
 METABOLIC  DAYS UNTIL  HYDROLYSIS  PHOTOLYSIS  METABOLIC  COMBINED
 (FIELD)  RAIN/RUNOFF  (POND)    (POND-EFF)   (POND)    (POND)
 ---------------------------------------------------------------------
 1336.00      0       N/A     .00-    .00   19.00    19.00


 GENERIC EECs (IN MICROGRAMS/LITER (PPB))    Version 2.0 Aug 1, 2001
 ---------------------------------------------------------------------
   PEAK    MAX 4 DAY    MAX 21 DAY   MAX 60 DAY   MAX 90 DAY
   GEEC    AVG GEEC     AVG GEEC    AVG GEEC    AVG GEEC
 ---------------------------------------------------------------------
    9.97      9.35       6.66       3.61       2.55
```

Scenario 3 – Use on citrus

```
 RUN No.  3 FOR Endosulfan     ON  Citrus      * INPUT VALUES *
---------------------------------------------------------------------
 RATE (#/AC)  No.APPS &  SOIL  SOLUBIL  APPL TYPE NO-SPRAY INCORP
 ONE(MULT)   INTERVAL   Koc  (PPB )   (%DRIFT)  (FT)    (IN)
---------------------------------------------------------------------
1.157(  2.306)  2  14  10600.0  330.0  ORCHAR(  9.7)    .0   .0
```

```
FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)
-----------------------------------------------------------------
METABOLIC  DAYS UNTIL  HYDROLYSIS  PHOTOLYSIS  METABOLIC  COMBINED
(FIELD)  RAIN/RUNOFF  (POND)    (POND-EFF)   (POND)    (POND)
-----------------------------------------------------------------
1336.00      2       N/A     .00-    .00   19.00    19.00


GENERIC EECs (IN MICROGRAMS/LITER (PPB))    Version 2.0 Aug 1, 2001
-----------------------------------------------------------------
  PEAK    MAX 4 DAY    MAX 21 DAY   MAX 60 DAY   MAX 90 DAY
  GEEC    AVG GEEC     AVG GEEC    AVG GEEC    AVG GEEC
-----------------------------------------------------------------
  16.45     15.56      11.12       6.04       4.28
```

Table 19: Summary of aquatic exposure

Scenario	Peak EEC (µg/l)	EEC (µg/l)			
		4 day	21 day	60 day	90 day
Max use rate as on label	13.2	12.4	8.9	4.8	3.4
Off-label turf use	10	9.4	6.7	3.6	2.6
Off-label citrus use	16.5	15.6	11.1	6.0	4.3

4.3.44 The GENEEC model is a deterministic model that calculates run-off and drift under standard conditions. Local conditions may differ from these standard conditions; certainly there will be variability that gives rise to a probability distribution of exposure concentrations. More sophisticated modelling has been conducted overseas to take account of such variability and this is described below.

4.3.45 Labels for endosulfan products in New Zealand specify no additional precautions, such as buffer zones, that should be taken to avoid environmental contamination although the label for Thionex Insecticide specifies that a strategy should be employed to minimise spray drift. Where such strategies are employed (and the approved handler control should ensure they are) the drift assumptions of the GENEEC model will overestimate exposure.

Tier II exposure modelling

4.3.46 No Tier II modelling has yet been performed to reflect New Zealand conditions and use patterns although as stated above, MCW may be able to provide New Zealand-relevant data during the public submissions period. Modelling performed overseas is not directly applicable to New Zealand. Nevertheless, the Agency has reviewed such modelling and includes a summary in Appendix D.

4.3.47 Subject to the caveat that overseas modelling is not directly applicable to New Zealand conditions or use patterns, this review highlights that under

US use conditions, USEPA (2007c) estimates of concentrations in receiving waters are similar to those estimated using Tier I modelling in New Zealand. The New Zealand use scenario most closely resembling the aerial application to tomatoes modelled by USEPA, is airblast application to citrus, giving rise to 9.7% and 5% spray drift respectively.

4.3.48 The expected environmental concentrations estimated by Ramanarayanan et al (1999), also for US use, are much lower due to their much lower estimates of spray drift.

Effects on aquatic organisms

4.3.49 The extensive database prepared by ANZECC 2000 has been used to determine effects concentrations for use in the risk assessment. The Agency used these data to determine HC_5 values for those higher taxa/compartment combinations (fish marine, fish freshwater, crustacea marine, crustacea freshwater) with more than 8 species. These values are set out in Table 20 below. Acute HC_5 values are concentrations at which the acute toxicity LC_{50}/EC_{50} is exceeded for 95% of species tested.

Table 20: HC_5 estimates of aquatic acute toxicity

Compartment	Taxon	Species count		HC_5 (µg/l)	Lowest LC_{50} (µg/l)
		Total	<Limit of solubility		
Freshwater	Fish	40	40	0.33	0.2
	Crustacea	24	21	0.16	0.1
	Molluscs	4	2	–	21
	Amphibia	1	1	–	1.9
Marine	Fish	11	11	0.12	0.1
	Crustacea	11	11	0.12	0.14
	Molluscs	6	6	–	2
	Annelids	2	1	-	196
	Echinoderm	1	1	-	230
	Red alga	1	1	-	80
Combined	Fish	51	51	0.24	0.1
	Crustacea	35	32	0.14	0.1
	All	101	93	0.2	0.1

4.3.50 The BurrliOZ software of ANZECC (2000) was used to determine which particular Burr Type III statistical distribution best fits the data. The software calculates the HC_5 from the distribution. Prior to calculating HC_5 values, the Agency excluded all data in which the toxicity value exceeded a water solubility of 0.33 mg/l and calculated a geometric mean where there was more than one datum for a species. The data are shown in Appendix B.

4.3.51 HC_5 values derived from these curves are summarised below. Lowest LC_{50} values have also been included which demonstrates that those taxa for

which there were insufficient data to generate a species sensitivity distribution, were no more sensitive than fish and crustacea.

4.3.52 The HC_5 values show that for acute exposures, freshwater crustacea are twice as sensitive as freshwater fish to endosulfan, but there is no difference between marine fish and crustacea. Marine taxa are more sensitive than freshwater.

4.3.53 For the risk assessment the acute HC_5 values for the freshwater fish (0.33 µg/l) and crustacea (0.16 µg/l) have been used. Marine taxa have been excluded on the grounds of reduced likelihood of exposure. Inclusion of marine data would increase the risk quotients by a maximum factor of 1.4 (derived as $fish_{freshwater}$ $HC_5/fish_{marine,\ freshwater}$ $HC_5 =$ 0.33/0.24).

4.3.54 A summary of chronic aquatic toxicity data is shown in Table 21. The Agency notes that ANZECC derived a 'high reliability' (chronic) HC_5 from these data of 0.02 µg /l. However, ANZECC recommend the use of the HC_1 of 0.03 µg /l, since the chronic HC_5 fails to protect some important Australian species from acute toxicity.

Table 21: Summary of chronic aquatic toxicity

Compartment	Taxon	Species count		Lowest NOEC (µg /l)
		Total	<Limit of solubility	
Freshwater	Fish	2	2	0.2
	Crustacea	3	3	2.7
	Green alga	1	0	–
	Protozoa	1	1	100

4.3.55 The lowest chronic NOEC is 0.2 µg /l (Table 21) which is an order of magnitude higher than the ANZECC chronic HC_5. The Agency has not used the lowest NOEC for the same reasons that ANZECC rejected the HC_5.

4.3.56 Given the comparatively low number of data used to calculate this HC_5, and ANZECC's recommendation to use the HC_1 as a guideline value, the Agency has investigated an appropriate acute/chronic ratio in order to determine a chronic NOEC from the acute HC_5. The ANZECC database contains acute and chronic test data for only the daphnids, *Ceriodaphnia dubia, Daphnia* magna and *Moinodaphnia macleayi* (Table 22). For these species the acute /chronic ratio is 19, 60 and 11 respectively (average 30). ANZECC (2000) does refer to a fathead minnow chronic value of 0.28 µg/l and an acute/chronic ratio of 3, but does not give the acute data used to derive the ratio. The chronic value is not in the ANZECC database. Consequently, the Agency considers this acute/chronic ratio cannot be taken into account.

Table 22: Acute/chronic aquatic toxicity ratios

Species	Acute LC_{50} (µg/l)	Chronic NOEC (µg/l)	Acute/chronic ratio
Ceriodaphnia dubia	188	10	19
Daphnia magna	161	2.7	60
Moinodaphnia macleayi	215	20	11

4.3.57 Given the lack of taxonomic diversity of species with both acute and chronic data, there is considerable uncertainty in extrapolating this acute/chronic ratio to other taxa. An acute/chronic ratio of 10 is considered more typical by the Agency. Applying this ratio to the acute HC_5 values gives chronic NOECs of 0.033 µg/l (fish) and 0.016 µg/l (crustacea).

4.3.58 The Agency has used chronic NOECs of 0.033 µg/l (fish) and 0.016 µg/l (crustacea) based on application of an acute/chronic value to the acute HC_5. This compares to the ANZECC guideline value based on an HC_1 of 0.03 µg/l.

4.3.59 The Agency notes the ANZECC (2000) report that fish were found in one lagoon with an endosulfan concentration of 0.22 µg/l, but in another lagoon sampled three days after a fish kill, the concentration was 0.15 µg/l.

4.3.60 There are few data available on the ecotoxicity of the metabolites of endosulfan and very few for species for which data are also available on endosulfan. Species for which a direct comparison can be made are shown in Table 23 and indicate comparable toxicity. USEPA (2007c) includes information on the toxicity of endosulfan sulphate to additional species for which data on endosulfan are not available. The Agency concludes that endosulfan sulphate appears as toxic as endosulfan, but data are too few to reach a conclusion on other degradates.

Table 23: Aquatic toxicity of endosulfan metabolites

Species	Endpoint	Endosulfan	Endosulfan sulphate	Endosulfan diol
Lepomis macrochirus (bluegill sunfish)	96 h LC_{50} (µg/l)	3.3[2]	3.8[1]	
Cyprinodon variegates (sheepshead minnow)	96 h LC_{50} (µg/l)	1.4[2]	3.1[1]	
Daphnia magna	48 h EC_{50} (µg/l)	188[2]		580[3]

[1] USEPA (2007c)

[2] Appendix B

[3] Health Canada (2007), duration not specified in report, assumed to be 48 h.

Aquatic Risk Quotients

4.3.61 The small amount of information on the toxicity of endosulfan sulphate suggests it is as toxic as the parent isomers. It is therefore appropriate that the exposure assessment take account of both endosulfan and endosulfan

sulphate. The Agency used DT_{50} values in the GENEEC2 modelling that took account of dissipation of both endosulfan and endosulfan sulphate. Solubility and K_{oc} were based on endosulfan which is slightly more hydrophobic than endosulfan sulphate (solubility and log Kow, 0.48 mg/l and 3.66 for endosulfan sulphate (experimental values from EPIWIN database), 0.33 mg/l and 4.55-4.77 for endosulfan. The difference in hydrophobicity between endosulfan and endosulfan sulphate will result in an underestimate of the expected environmental concentrations.

4.3.62 The Agency has calculated risk quotients using the GENEEC2 estimates of environmental concentrations. Use of the USEPA (2007c) estimates would have little effect on the Agency's analysis given the similar EEC. Use of the MCW's EEC values would give rise to lower risk quotients primarily due to the much lower estimates of percentage drift (6-300 times lower). However, this is not applicable since these estimates incorporate a 31-91 m drift buffer zone around the crop which is not currently mandated in New Zealand.

4.3.63 The time-relevant EEC for risk assessment should be selected based on the duration of the toxicity tests. For an acute exposure assessment it is appropriate to compare the peak EEC to the acute HC_5. When a chronic NOEC is derived from a specific test, the duration of the exposure used to derive the risk quotient, should be the duration of the toxicity test or as close to it as possible. The Agency has elected to use a 21 day EEC, this being the duration of a chronic *Daphnia* study and the closest time period to the duration of a standard fish early-lifestage test (35 days).

4.3.64 The resultant risk quotients are shown in Table 24.

Table 24: Calculation of RQs

	Peak EEC from GENEEC2 (µg/L)	Acute ecotoxicity HC_5		RQ (acute)
		Species	Value (µg/l)	
Label use	13	Fish	0.33	39
		Crustacea	0.16	81
Turf use	10	Fish	0.33	30
		Crustacea	0.16	63
Citrus use	17	Fish	0.33	52
		Crustacea	0.16	110

	21 day EEC from GENEEC2 (mg/L)	Chronic ecotoxicity (0.1 x acute HC_5)		RQ (chronic)
		Species	Value (mg/l)	
Label use	8.9	Fish NOEC	0.033	270
		Crustacea	0.016	560
Turf use	6.7	Fish NOEC	0.033	200
		Crustacea	0.016	420
Citrus use	11.1	Fish NOEC	0.033	340
		Crustacea	0.016	700

4.3.65 When compared against the relevant levels of concern (LOC) listed in Table 16, the RQs derived from the GENEEC 2 modelling for endosulfan indicate high acute and chronic risk to freshwater fish and invertebrates.

4.3.66 Monitoring of residues in marine mammals has been reported overseas. The Agency is unaware of any information on seawater or biota concentrations of endosulfan in waters around New Zealand. This area of potential risk has therefore not been assessed.

Overseas risk assessments

USEPA

4.3.67 USEPA (2007c) estimate freshwater RQ based on the EEC described in Appendix D, the ranges reflecting the different use patterns for which exposure was estimated as follows:

	Fish	Invertebrate
Acute	15–28	2.1–4.0
Chronic	36–62	79–133

4.3.68 These RQs are lower than those calculated by the Agency for New Zealand. This arises from differences in the toxicity measures used, particularly for acute invertebrate toxicity, since the exposure concentrations are similar. USEPA used lowest LC_{50}/EC_{50} and NOEC values from a more limited dataset than the ANZECC (2000) database used by the Agency.

Canada

4.3.69 Health Canada (2007) performed separate exposure analyses for the risks posed by runoff and spray drift arguing that different measures might be taken to control the different routes of input.

4.3.70 PRZM/EXAMS was used to calculate runoff contamination of water bodies adjacent to application sites (i.e. drift in the model was set to zero). Exposure under eight combinations of location, crop and application rate were modelled probabilistically. Species sensitivity distributions of acute LC_{50} and of chronic NOEC values were used to determine the percentage of species expected to be affected. The combined analysis indicated that for all but one of the scenarios there was a high probability of effects, for example, a 40% probability of exceeding the acute LC_{50} in 50-90% of freshwater fish, a 98-99.9% probability of exceeding the chronic NOEC for freshwater fish. Health Canada add that given the persistence of endosulfan and endosulfan sulphate in soil, a buffer zone may not be effective in avoiding run-off risks to aquatic habitats, and national trials of the effectiveness of vegetative strips to reduce contamination would be needed to clarify this.

4.3.71 Health Canada's estimates of the size of buffer zones required for the protection of aquatic habitats from spray drift are set out in Table 25 below.

Table 25: Health Canada's estimate of buffer zones required for aquatic habitat protection from spray drift

Method of application	Buffer zone (m) required for the protection of aquatic habitats (non-exceedance of levels of concern) at water depths:					
	Freshwater habitat			Estuarine/marine habitat		
	<1 m	1–3 m	>3 m	<1 m	1-3 m	3 m
Field sprayer	120	120	70	120	120	120
Airblast (early season)	80	70	60	100	90	80
Airblast (late season)	70	60	50	90	80	70

Australia

4.3.72 APVMA (1998) estimate that spray drift from an application of 700 g a.i/ha would need to be reduced to less than 0.1% to prevent effects in a 15 cm deep water body. Their estimate is that this would require a buffer zone exceeding 150 m.

Makhteshim (MCW)

4.3.73 Ramanarayanan et al (1999) superimpose an acute toxicity species sensitivity distribution (HC_5 approximately 0.09 µg/l) on their EEC probability distribution, based on a 91 m buffer zone. The highest 90th percentile peak EEC for any crop is 0.37 µg/l, at which concentration it is estimated 13.3% of species would be affected. Ramanarayanan et al (1999) claim that, since the distributions of exposure and effects are independent, the overall probability of any organism being affected will be the product of the probability of exposure and effect, i.e. 0.1x13.3 = 1.3%. However, the Agency is of the view that the critical issue is whether any species would be affected, rather than whether there is a probability of a specific species being affected. The estimate that 13.3% of species would be affected at the 90th percentile peak EEC is therefore the critical parameter.

Terrestrial Risk Assessment

Terrestrial exposure – monitoring

4.3.74 Monitoring of the terrestrial environment is included in the studies listed in Appendix C.

Terrestrial Exposure – modelling

Soil invertebrates

4.3.75 The strong sorption of endosulfan to soil will tend to reduce movement of the substance and its metabolites in the soil column. The Agency has assumed that endosulfan residues will mix within the top 5 cm of the soil. Assuming a dry soil density of 1.5 and a maximum treatment rate of 4 applications at 0.7 kg a.i./ha, the maximum concentration in soil within a treated field would be 3.7 mg/kg soil (dry weight). The surface litter concentration, on which some earthworms feed, would be expected to be

higher, possibly as high as 160 mg/kg based on the short grass category of Fletcher et al (1994), although it would decrease quite rapidly due to volatilisation.

4.3.76 Adjacent to a treated field, the concentration derived from spray drift would decrease with distance from the field reflecting the deposition pattern. The concentration derived from run-off would be spatially highly variable depending on the flow of particles from the field, with a maximum of 3.7 mg/kg soil (dry weight).

Bees and other terrestrial invertebrates

4.3.77 Bees, and other invertebrates, may be directly exposed if present in a field that is sprayed or off-field due to drift. Deposition from spraying at 0.7 kg/ha would amount to about 7µg/cm^2 which is about the area of a bee (Davis & Williams, 1990). Such insects would also be subsequently exposed by contact with sprayed surfaces and volatilised endosulfan. Conversely, volatilisation of endosulfan from plant surfaces will reduce direct exposure over time.

Terrestrial effects – plants, terrestrial invertebrates, soil micro-organisms and birds

4.3.78 There are few studies investigating effects of endosulfan on plants. USEPA's ECOTOX database lists studies with 11 species under a variety of conditions. The records provide few details, for example, in most cases the formulation tested is not recorded (Appendix B). The Agency has not examined the source documents for these studies, but the overall impression is of a lack of plant toxicity at the concentrations tested. The Agency performed no analysis of the risk to plants.

4.3.79 Reports of endosulfan concentrations that cause effects in laboratory tests are shown in Table 26. These data are used in the Agency's risk assessment and qualified by field observations.

Table 26: Terrestrial invertebrate toxicity used in the risk assessment

Taxon	Exposure route	Result	Reference
Earthworms (*Eisenia andrei*)	Laboratory artificial soil	14 d LC_{50} = 9.4 mg/kg	Heimbach (1985)
Earthworm (*Lumbricus terrestris*)	Laboratory, natural soil	14 d LC_{50} = 9 mg/kg	Haque and Enbing 1983, cited in Heimbach 1985
Bees (*Apis mellifera*)	Laboratory Oral Contact	 48 h LD_{50} = 2 µg/bee 48 h LD_{50} = 2.4 µg/bee	APVMA (1998)

4.3.80 The toxicity of endosulfan to non-target invertebrates other than bees and earthworms has been reported in several publications, but critical information needed to evaluate these reports is lacking (Appendix B). For example, Brasse (1985) reviews information on toxicity to a wide range of non-target invertebrates but details of the endosulfan formulation used, concentrations causing effects and the nature of the effects are not clear in

the publication, and effects are reported subjectively, varying from 'none to 'severe'. Biobest (2008) also report the relative toxicity of endosulfan to many species of non-target invertebrates, it is thought under laboratory conditions although it is stated that results were verified in trials under field conditions. Biobest (2008) do state that their list is based on results obtained under Western European horticultural and climatic conditions, but the application rates used are not stated. Their results suggest >75% death in many species particularly parasitoids (Appendix B).

4.3.81 Boller et al (2005) report that endosulfan is toxic to parasitoids (*Trichogramma cacoeciae*) under laboratory conditions, but not to lacewings (*Chrysoperla carnea*) under laboratory conditions, The IOBC (Boller et al 2005) indicate that endosulfan is not toxic to bees. Bastos et al (2006) also report toxicity to the parasitoid, *Trichogramma pretiosum* in laboratory tests in which host eggs were treated by dipping in 2.92 g a.i./l solution for 5 seconds.

4.3.82 MCW has reported to the Agency that a specific detoxification system has been identified in beneficial insects (species not specified) by which endosulfan is actively detoxified via the Glutathion-S-Transferase System (GSTs), which conjugates the molecule of endosulfan to the three-peptide glutathion, thus making the molecule unable to bind its target, the GABA receptor. The GST system has demonstrated a lower activity in most of the target pests. Kern (1990) reports that endosulfan is metabolised more rapidly and effectively in the honey bee than the cabbage white butterfly and also that bees have notably active mixed function oxidase and GST enzyme systems. Endosulfan is also reported to have little insecticidal action against ladybirds (*Coccinella septempunctata*) and some parasitic hymenoptera (*Cephalonomia stephanoderes* and *Prorops nasuta*) (Kern 1990). Nath et al (1985) report metabolic pathways of endosulfan, with excretion via conjugates of endosulfan diol, endosulfan ether and endosulfan hydroxyether, but do not comment on the relative abilities of bees and other non-target organisms versus pest species.

4.3.83 Effects concentrations used by the Agency in the bird risk assessment are set out in Table 27 below.

Table 27: Summary of bird toxicity data

Species	Exposure route	Test results		Reference
		Endosulfan	Endosulfan sulfate	
Mallard (*Anas platyrhynchos*)	Oral	Acute LD_{50} 28 mg/kg bw		APVMA, 1998
	Diet	Acute LC_{50} 1053 mg/kg diet		USEPA, 2002;
	Diet	24 week, chronic NOAEC 30 mg/kg diet LOEC 60 mg/kg diet – growth and egg production affected		USEPA, 2002; APVMA, 1998

Species	Exposure route	Test results		Reference
	Diet		Acute LC_{50} 1642 mg/kg diet NOEC 170 mg/kg diet [clinical signs of toxicity, bodyweight, feed consumption]	USEPA 2007c
Northern bobwhite quail (*Colinus virginianus*)	Diet	Acute LC_{50} 805 mg/kg diet		USEPA, 2002;
	Oral		Acute LD_{50} 44 mg/kg bw NOEL 35 mg/kg bw [feed consumption]	USEPA 2007c
	Diet		Acute LC_{50} >3528 mg/kg diet NOEC 367 mg/kg diet [bodyweight and feed consumption]	USEPA 2007c

Terrestrial Risk

Risk to soil organisms

4.3.84 Comparison of the 14 day earthworm laboratory LC_{50} 9 mg/kg with the EEC based on four field applications of 0.7 kg a.i./ha and mixing of endosulfan into the top 5 cm of soil (EEC = 3.7 mg/kg) would suggest that acute effects are unlikely. Chronic toxicity data are not available for effects on earthworms. However, treatment at rates as low as 1.1 kg/ha is used to control moderate to severe earthworm problems (B. Walmsley pers.comm.). The difference between what is expected on the basis of laboratory toxicity and what may be seen in the field may be due either to earthworms feeding on the litter layer with higher residues than are assumed based on homogeneous residues within the top 5 cm of soil, or to differences in the degradation rates in laboratory tests and the field compared to the relative toxicity of endosulfan and its degradates. Effects on earthworm populations under labelled application rates (0.7 kg a.i/ha, which may be repeated), are therefore to be expected.

4.3.85 Joy & Chakravorty (1991) report that populations of collembola and total microarthropods were significantly reduced 45 days after an application (dose given as 0.33%, but the application rate is not stated). After 75 days, soil residual toxicity remained to the larvae of the mite genus *Lancetoppia* (41% mortality) and the collembolan genus *Cyphoderus* (43% mortality).

4.3.86 Vig et al (2008) report on the populations of microbes in fields treated sequentially with a series of insecticides including endosulfan, but the text and figures are conflicting. The Agency has not used this report in its assessment.

Risk to plants

4.3.87 There are no data indicating toxicity of endosulfan to plants and the Agency is unaware of any reports of phytotoxicity from the field. Therefore, the risks to plants from exposure to endosulfan have not been evaluated.

Risk to bees and other non-target invertebrates

4.3.88 Deposition onto a 1 cm^2 bee from an application at 0.7 kg a.i./ha would amount to about 7 µg/bee, which is more than the laboratory contact LD_{50} (2.4 µg a.i./bee). Effects on bees might therefore be expected. One early study from New Zealand (Palmer-Jones et al, 1959) in which 1 acre of a 25 acre crop of brassicas treated at 1.3 kg/ha showed 60-67% mortality of bees picked from the crop in the 30 hours following application, dropping to 8% by 6 days after application. However, no effects were observed at the hives. The authors stress that only 4% of a larger crop was treated. Another study with an application rate of 2.2 kg/ha appeared to show a deterrent effect on bees released one hour after treatment which persisted for >3 hours (Palmer-Jones, 1959). Other trials in Germany, at lower application rates, showed no effects and a review of 3947 reports of damage to bees in Germany over a 14 year period in the 1970's and early 1980's indicated only one report attributable to endosulfan (Brasse, 1985). MCW has reported to the Agency that endosulfan is favoured in integrated pest management programmes for its relative lack of effect on beneficial invertebrates (Makhteshim, pers.comm.).

4.3.89 The extent of the risk to other non-target terrestrial invertebrates is similarly unclear. Laboratory data (Appendix B) suggest toxicity, particularly to parasitoids, but field observations suggest this toxicity may not occur at current application rates.

4.3.90 APVMA (1998) report that endosulfan is less of a hazard (sic) to non-target organisms than alternative insecticides due to rapid dissipation through volatilisation.

4.3.91 The Agency concludes that endosulfan is toxic to bees and many non-target organisms in laboratory testing, but there is uncertainty as to whether such effects occur in the field.

Risk to birds feeding in fields

4.3.92 Based on the LD_{50} value of 28 mg/kg bw to Mallard ducks (*Anas platyrhynchos*) of endosulfan is considered highly toxic to birds on an acute exposure basis. Chronic toxicity data on ducks (NOEC = 30 mg/kg diet) revealed that reproduction and growth were the most sensitive endpoints (USEPA, 2002).

4.3.93 The EEC values were derived using the USEPA Terrestrial Residue Exposure (T-Rex) Model version 1.2.3.[17]

[17] http://www.epa.gov/oppefed1/models/terrestrial/index.htm

4.3.94 The values for this model are derived from the Kenaga nomograph, as modified by Fletcher et al. 1994. Risk quotients are based on the most sensitive LC_{50} (805 mg/kg diet, Bobwhite quail) and NOEC (30 mg/kg diet, Mallard duck) for birds (Table 27).

4.3.95 Acute and chronic risk quotients were calculated following the procedure outlined in Appendix F and were compared to levels of concern (LOCs) outlined in Table 16.

4.3.96 Acute high risk LOCs (Table F1, Appendix F) were exceeded for birds for one of the three use patterns modelled (turf use) (RQ range: 0.01 - 0.56). Chronic LOCs were exceeded (RQ range: 0.38 – 14.99) for all use patterns modelled when the peak EEC was used. When the 56 day mean EEC was used, chronic LOCs, although lower, were still exceeded for all use patterns examined (RQ range: 0.1–2.20).

4.3.97 As a result of the exceeded LOCs using the USEPA sourced foliar dissipation half-life of 4 days (USEPA 2002), the Agency refined the assessment by using the minimum foliar dissipation half-life of 0.95 days sourced by MCW (Ramanarayanan et al, 1999a).

4.3.98 The source of the USEPA foliar dissipation half-life of 4 days is based on the upper 90^{th} percent confidence interval value for the mean of 8 reported half-life studies on a variety of crops including: cotton, grapes, pears, tobacco, alfalfa, beets, and leafy vegetables. However, the reported results did not distinguish between foliar degradation, plant uptake, wash-off, or volatilisation as routes of dissipation (USEPA, 2002).

4.3.99 The addition of this factor did not significantly alter the acute and chronic RQs when the peak EECs were used (Table F2, Appendix F). However, when the 56 day mean EEC was used chronic LOCs, no longer exceeded the LOC (RQ range: 0.03 – 0.68).

4.3.100 USEPA (2002) used RQs to assess the risk to birds (and mammals). Only the results of the analysis are presented and the conclusion is that even a single application of 1.14 kg/ha will give rise to a concentration on short grass that will lead to a risk that could be mitigated by restricted use. The report stresses there is uncertainty in this conclusion due to lack of data on interception and subsequent dissipation from leaves. However, the analysis was for parent endosulfan only and, as mentioned above, the sulphate metabolite may be similarly toxic. The TER derived from multiple applications (3 x 1.14 kg/ha at 7-day intervals) indicates acute risks that may be mitigated through restricted use and chronic risks.

4.3.101 Health Canada performed a similar analysis and estimated that passerines of the size of sparrows may be at risk because it would take 0.2-1 hours consumption of food from an area contaminated with endosulfan to reach the acute oral NOEL. Chronic risks are expected for birds the size of mallard following repeat applications at a rate of 800 g a.i./ha.

4.3.102 APVMA, however, concluded that an application rate of 2.1 kg/ha would leave a dietary residue approximating half the dietary LC_{50} and concluded that the risk to birds is low.

4.3.103 The conclusion drawn by the Agency from these analyses is that, using the foliar dissipation input data value from the USEPA (USEPA 2002), the acute RQ exceeded the LOC for birds feeding on short grass following 'off label' use for turf. However, each use pattern examined led to the chronic RQ (peak EEC) exceeding the LOC for the majority of feeding scenarios. Following refinement to the 56 mean EEC, each use pattern still had at least one feeding scenario that exceeded the chronic LOC.

4.3.104 This above model was further refined by using the foliar dissipation data value recommended by MCW. Although the acute RQ still exceeded the LOC for birds as above, no chronic RQ exceeded the LOC for any use pattern examined when the 56 day EEC was used with this foliar dissipation data value.

4.3.105 Validation of this refinement option via the assessment of the primary reference source required before any firm conclusion of the chronic risk to birds can be drawn. Regardless, there is an acute risk to birds associated with the 'off-label' use of endosulfan on turf.

Risk to birds feeding in water

4.3.106 USEPA (2007c) includes an assessment of risk to birds feeding in water (belted kingfisher, herring gull, osprey, mallard, great blue heron, bald eagle) and aquatic mammals (mink, river otter). The analysis uses a food web model (Arnot & Gobas, 2004) to estimate the concentration in food items in various aquatic trophic levels, using the 60 day average concentrations derived from PRZM/EXAMS modelling as the water exposure concentration. The model has the following stages:

- Monte Carlo simulation (10000 trials) was used to predict the range (mean, standard deviation and 90 percentile) of body residues, BCF and BAF values at each trophic level. The analysis showed that endosulfan body residues are not predicted to increase across aquatic trophic levels when lipid-normalised;
- The derived body residue concentrations were applied to estimate the exposure through food of the birds and mammals mentioned previously;
- Exposure through water intake is added to estimate the total dietary exposure;
- Acute and chronic toxicity data for tested bird species (northern bobwhite quail and mallard) were normalised by bodyweight;
- Risk quotients for both dose-based (µg endosulfan/kg-bw/day) and dietary-based (µg pesticide/day) exposure were calculated with LOCs specified as 0.1 (acute toxicity) and 1.0 (chronic toxicity).

4.3.107 The analysis resulted in exceedence of the acute LOC at the 90th percentile exposure concentration using a dose-based analysis but not a diet-based analysis, for belted kingfisher (and mink, and river otter). Chronic exposures were all less than the LOC, reflecting the relative differences of acute LD_{50}/chronic NOEC compared to the acute/chronic LOC.

4.3.108 The relevance of this analysis to New Zealand is summarised as follows:

- The aquatic exposure concentrations used in the USEPA (2007c) analysis used a range of 0.1–5.0 µg/l compared to the Agency derived values of about 4.0 µg/l.
- The Agency converted the results of the bird analyses to relevant New Zealand species using bodyweights and diet of New Zealand species as listed in Heather & Robertson (1996), and the food residues and algorithms given in USEPA, 2007c. This analysis is shown in Appendix F. The results of this analysis are set out in Table 28.

Table 28: Risk assessment for birds feeding on aquatic organisms

Diet modelled	Bird weight (g)	Species	Typical food	Residue in diet items (from USEPA, 2007c)	Risk Quotient		
					Acute		Chronic
					Dose	Dietary	Dietary
Piscivorous fish	550	White-faced heron (male)	Fish, frogs, tadpoles, aquatic and pasture insects, spiders, earthworms and mice	90 percentile	0.069	0.0013	0.034
Piscivorous fish	1100	Australasian Crested Grebe	Fish, aquatic inverts	90 percentile	**0.11**	**0.0040**	**0.11**
Piscivorous fish, benthic invertebrates (75:25)	1100	Australasian Crested Grebe	Fish, aquatic inverts	90 percentile	0.10	0.0038	0.10
Piscivorous fish	1100	Australasian Crested Grebe	Fish, aquatic inverts	Mean	0.043	0.0016	0.043
Phytoplankton zooplankton, benthic invertebrates (34:33:33)	1300	Mallard (male)	Aquatic invertebrates plants	90 percentile	0.041	0.0018	0.048
Invertebrates	600	Brown teal (male)	Invertebrates	90 percentile	0.024	0.00050	0.013

4.3.109 The risk quotients derived for New Zealand species show that, other than for a large water bird feeding exclusively on piscivorous fish, and assuming a 90 percentile residue concentration based on US use patterns, the risk to aquatic birds would not exceed the LOC (0.1 for acute, 1.0 for chronic). The risk is therefore considered low.

4.3.110 The Agency has not undertaken a risk assessment for birds feeding on earthworms.

Conclusion to environmental risk assessment

4.3.111 The Agency concludes:

- There is a high acute and chronic risk to aquatic species (fish and invertebrates) from all current uses of endosulfan in New Zealand. This conclusion is based on lower sensitivity environmental exposure modelling.
- Exposure of non-target areas, including the aquatic environment, can be reduced by the use of buffer zones. Such buffer zones would need to be substantial, possibly extending over 100 metres.
- There is a risk to earthworms when endosulfan is used in accordance with label uses. Runoff from use could lead to risks to earthworms and soil arthropods outside the application area. Endosulfan is used to control earthworm populations under specific circumstances including use on sports fields and grass areas at airports.
- Laboratory data suggests that endosulfan is toxic to bees and other non-target terrestrial invertebrates. There is uncertainty as to whether such effects occur in the field.
- There is no indication of risks to plants.
- There may be a risk to birds feeding in fields where crops have been recently treated. There is an acute risk to birds associated with the use of endosulfan on turf.
- The risk to water birds is low. Using a conservative model there is some risk to large water birds which feed exclusively on piscivorous fish.

4.3.112 No assessment can be made of the risk to marine mammals (seals, dolphins) due to an absence of New Zealand-based data. However, contamination of remote regions through long-range movement of endosulfan is likely based on overseas monitoring. ERMA New Zealand has not considered this aspect of the risk of use of endosulfan as part of this reassessment. It is more appropriate for this risk to be addressed at the international level through the Stockholm and Rotterdam Conventions.

Assessment of human health risks

Introduction

4.3.113 Human health risks occur as a result of the inherent toxicity of the substance and exposure to the substance in various scenarios. For the lifecycle of endosulfan, the activities and associated sources of risk have been identified in Table 14.

4.3.114 The risks to consumers exposed to endosulfan residues in food have not been considered by the Agency in this reassessment, as dietary exposures and risks are evaluated by the New Zealand Food Safety Authority under the Food Act 1981.

4.3.115 Potentially significant risks to human health might arise from accidents during importation, transportation or storage. However, the likelihood of such accidents is deemed to be highly improbable, and the first response to such accidents is likely to be by facility staff and/or emergency personnel trained in the containment and disposal of hazardous substances.

4.3.116 Risks associated with the disposal stage of the lifecycle were also assessed as being very low on the basis that responsible disposal of empty containers or un-used product by the user (agri- or horticulturalists; turf consultants etc) will occur. These users are required to hold Approved Handler and GROWSAFE® certificates that cover safe use and disposal. The empty drums can be returned through one of 52 District Council approved "Agrecovery" recycling sites.

4.3.117 Conversely, the probability of possible exposure during normal agricultural use is relatively high, and the risks have been estimated for various occupational activities (during mixing/loading and application, and post-application) and bystanders/residents in different scenarios (at application and post-application), and are described in the following sections.

Scenarios evaluated:

4.3.118 Use patterns are discussed in detail in Section 3. In the human health risk assessment risks from the following uses are evaluated:

- Label use: 0.7 kg a.i./ha, using boom sprayer with hydraulic nozzles;
- Turf use: 2.1 kg a.i./ha, using boom sprayer with hydraulic nozzles;
- Citrus use: 1.3 kg a.i./ha, using an airblast sprayer;
- Application by hand-held sprayer: 0.7 kg a.i./ha using a hand-held sprayer with hydraulic nozzles.

Acceptable Operator Exposure Level (AOEL):

4.3.119 Occupational exposures are compared against a health benchmark, the Acceptable Operator Exposure Level (AOEL), to give an estimate of risk.

4.3.120 The AOEL is based on the most sensitive, relevant NOAEL or LOAEL, in terms of duration, target population, and dose/exposure route available for the substance.

4.3.121 Factors are applied to modify the NOAEL/LOAEL to account for the uncertainties in extrapolating from test species to humans, and to account for any differences in duration, route etc.

4.3.122 The NOAEL/LOAELs are usually derived from short or medium term animal studies with the appropriate uncertainty factors and are designed to protect against repeat exposure over several months. NOAEL/LOAELs with lower uncertainties may be preferred.

4.3.123 As New Zealand endosulfan formulation labels do not specify the frequency of use during the growing season, the Agency has noted that the information supplied which indicates one or two applications per year. However, spraying contractors may be exposed intermittently over the whole spraying season. Therefore the AOEL has been based on studies of short (1-30 days) to intermediate (1-6 months) duration.

4.3.124 Relevant NOAEL/LOAELs from the endosulfan toxicology data packages considered by the Agency are as follows:

- Dietary developmental neurotoxicity (DNT) study in rats (Gilmore et al., 2006 in Cal DPR, 2008)
  - LOAEL = 3.74, based on decreased pup weight; NOAEL not established.
  - Uncertainty factors: 10x interspecies; 10x intraspecies; 3x LOAEL→NOAEL.
  - 100% oral absorption factor [US EPA used 100%; Cal DPR used 100%].
  - AOEL = 0.012 mg/kg b.w./day [using uncertainty factors of 300].
- 21-day inhalation toxicity study in rats (Hollander et al., 1984 in Cal DPR, 2008)
  - NOEL = 0.2 mg/kg b w/day, LOAEL = 0.002 mg/L, based on decreased body weight gain and alterations in haematology and clinical chemical parameters.
  - Uncertainty factors: 10x interspecies; 10x intraspecies.
  - 100% inhalation dose to absorbed dose. [US EPA used 100%; Cal DPR used 100%].
  - AOEL = 0.002 mg/kg b.w./day [using uncertainty factors of 100].
- 21-day dermal toxicity rat study (Ebert, Leist & Kramer, 1985 in Cal DPR, 2008)
  - NOAEL = 9 mg/kg b w/day, LOAEL = 27 mg/kg b w/day based on mortality.
  - Uncertainty factors: 10x interspecies; 10x intraspecies.
  - 0.5% dermal absorption for concentrates i.e. mixing/loading, 1.52% for spraying. [US EPA used 45%; PMRA, 47%; Cal DPR, 47.3%].
  - AOEL = 0.0045 mg/kg b.w./day [using uncertainty factors of 100, and a dermal absorption factor of 0.5%].

  - [Note: a previous 21-day dermal toxicity rat study (Ebert, Weigand & Kramer, 1985 in Cal DPR, 2008) gave NOAEL = 12 mg/kg b w/day, LOAEL = 48 mg/kg b w/day based on mortality, but was repeated due to technical problems.] [Also see Thevenaz, et al., 1988 in Cal DPR, 2008 using a 33.3% EC formulation.]

- 13-week dietary study in rats (Barnard et al., 1985 in Cal DPR, 2008)
  - NOEL = 1.92 mg/kg b w/day, LOAEL = 3.85 mg/kg b w/day increases in kidney weights and granular formation in kidney proximal tubule cells.
  - Uncertainty factors: 10x interspecies; 10x intraspecies.
  - 100% oral absorption factor [US EPA used 100%; Cal DPR used 100%].
  - AOEL = 0.019 mg/kg b.w./day [using uncertainty factors of 100].
- 2-generation dietary study in rat (Edwards et al., 1984 in Cal DPR, 2008)
  - NOEL = 1.18 mg/kg b w/day, LOAEL = 6.18 mg/kg bw day based on increased relative liver and kidney weights, decreased food consumption & decreased body weights.
  - Uncertainty factors: 10x interspecies; 10x intraspecies.
  - 100% oral absorption factor [US EPA used 100%; Cal DPR used 100%].
  - AOEL = 0.012 mg/kg b.w./day [using uncertainty factors of 100]
- Combined chronic/carcinogenicity study in rats (Ruckman et al., 1989 in Cal DPR, 2008)
  - NOEL = 0.6 mg/kg b w/day, LOAEL = 2.9 mg/kg b w/day based on reduced body weight gain, increased incidences of marked progressive glomerulonephrosis and blood vessel aneurysms in male rats.
  - Uncertainty factors: 10x interspecies; 10x intraspecies.
  - 100% oral absorption factor [US EPA used 100%; Cal DPR used 100%].
  - AOEL = 0.006 mg/kg b.w./day [using uncertainty factors of 100].
- 1-year dietary dog study (Brunk, 1989 in Cal DPR, 2008)
  - NOEL = 0.57 mg/kg b w/day, LOAEL = 2.09 mg/kg b w/day based on premature deaths (not spontaneous), neurotoxicity.
  - Uncertainty factors: 10x interspecies; 10x intraspecies.
  - 100% oral absorption factor [US EPA used 100%; Cal DPR used 100%].

– AOEL = 0.0057 mg/kg b.w./day [using uncertainty factors of 100].

4.3.125 The Agency concludes the DNT study used by US EPA incurs additional uncertainty, as no NOAEL was established, whilst the dermal studies involve uncertainty around dermal absorption factors, as expressed by the lack of an international consensus. The 21-day inhalation study (Hollander et al., 1984 in Cal DPR, 2008) was considered to be of too short duration to adequately cover possible seasonal exposures.

4.3.126 Among the dietary studies, referred to above, the 13 week study of Barnard et al (1985 in Cal DPR, 2008) is robust in comparison to other available values, duration of the study (seasonal), and target population (male and female workers). Therefore the Agency has used the NOAEL of 1.92 mg/kg b w/day from the 13-week dietary study in rats (Barnard et al., 1985 in Cal DPR, 2008) as the relevant benchmark for occupational exposures of workers on short-term and seasonal basis.

4.3.127 As the AOEL is a measure of total systemic exposure or absorbed dose, an oral absorption factor is required to extrapolate from a NOAEL derived from an oral animal study. A 100% oral absorption factor seems to be the most robust on available evidence and has been used by US EPA and Cal DPR.

4.3.128 The Agency's use of the NOAEL of 1.92 mg/kg b w /day from the 13-week dietary study in rats (Barnard et al., 1985 in Cal DPR 2008) incurs the minimum level of uncertainty for an animal model to estimate an absorbed dose: uncertainty factors of 10 and 10 to account for intra- and interspecies variation, with no correction factor for oral absorption since it is considered to be 100%:

$$\textbf{AOEL} = \frac{(1.92 \text{ mg/kg bw/day})}{(10 \times 10)} = \textbf{0.0192 mg/kg b.w./day}$$

4.3.129 Overseas regulators have used other studies to set their occupational benchmarks. [Note: The BBA occupational exposure model out-puts total systemic exposure, which can be compared against the AOEL. However, the US models keep the exposures separated by route and are compared to route specific NOAELs, and the Margin of Exposure (MOE, equivalent to the Risk Quotient (RQ)) incorporate any uncertainty factors]:

- **USEPA (2007)** has argued that the DNT LOAEL is the most suitable short-term and intermediate benchmark for assessing dermal exposures and ingestion, as this value is protective of the most sensitive population (young women), plus testing through gestation and lactation. An additional factor of 3 was used to account for using an LOAEL instead of an NOAEL.

"Previously, two available 21-day dermal toxicity rat studies were the basis of quantifying dermal risk. The dermal NOAEL was 12 mg/kg/day with a LOAEL of 48 mg/kg/day based on mortality. However, the results of the recently submitted DNT shows concern for offspring toxicity (decreased pre-weaning body weight) which is not evaluated in the 21-day dermal study (conducted in adult animals only). Additionally, the DNT was examined to address the concern for changes in the uterine and pituitary weights that were seen in adults at the highest dose only (6.2 mg/kg/day) in the two-generation reproduction study. The use of an offspring endpoint from the DNT study (LOAEL = 3.7 mg/kg/day) is the most appropriate endpoint in order to be protective of the most sensitive population (female workers). This decision is supported by the pup weight decrements being observed only during lactation (i.e., the pup body weights were not affected at birth AND the pups recovered after post-weaning (PND 22)) and therefore are likely due to nursing. Furthermore, the 2-generation reproduction study (MRID 00148264) noted a similar effect (decrease litter weight) during the lactation to weaning period in both matings in the F0 generation, which was significant at the high dose (6.18 mg/kg) level in the first mating and at the mid (1.23 mg/kg) and high dose (6.18 mg/kg) levels in the second mating. Since a NOAEL was not established in the DNT, a LOAEL to NOAEL factor is necessary for the dermal assessment. Based on the degree of pup weight loss in the DNT and pup weight loss in the 2-generation reproduction study, a 3X is most appropriate. The dermal absorption factor of 45% remains consistent with the 2002 assessment" [quote US EPA, 2007].

As US EPA use different NOAELs for dermal and inhalation exposures of each time duration, a NOAEL of 0.2 mg/kg bw/day from a 21-day rat inhalation study was chosen for short- and seasonal-inhalation exposure scenarios.

- **APVMA**: For OHS risk assessment the 13-week dietary study in rats (Barnard et al., 1985) is considered relevant to compare total systemic exposure as endosulfan is used on a seasonal basis. The toxicology review concluded the NOEL to be 1.92 mg/kg b w/day LOEL = 3.85 mg/kg b w/day [APVMA, 1998]. This key study was kept for the 2005 re-assessment [APVMA, Vol2 2005 OHS].
- **Cal DPR**: Use different NOAELs for dermal and inhalation exposures.
  - Critical Acute Oral NOEL (used for dermal MOE determination) = 0.7 mg/kg (Rabbit Developmental study (Nye, 1981): salivation, convulsions/thrashing, noisy/rapid breathing, hyperactivity salivation and nasal discharge).
  - Critical acute Inhalation NOEL was 0.194 mg/kg/day (Hollander et al., 1984; rat subchronic inhalation study).

- Critical Subchronic (seasonal) Oral NOEL (used for dermal MOE) was 1.18 mg/kg/day (Edwards et al., 1984; 2-generation dietary study in rat). Two studies were considered acceptable according to FIFRA Guidelines (13-week dietary study in rats, Barnard et al., 1985; 2-generation dietary study in rat, Edwards et al., 1984), the reproduction study is preferable because it provides the lower NOEL. Therefore, the reproduction study in rat was selected as the definitive study.
- Critical Subchronic (seasonal) Inhalation NOEL was 0.194 mg/kg/day (Hollander et al., 1984; rat subchronic inhalation study).

For Cal DPR, the DNT study removes a data gap that caused them to use a 3x factor in their Food Quality Protection Act (FQPA) risk assessment calculations. They did not consider, in contrast to the US EPA, that it represented the key study for short-term and intermediate assessment of dermal exposures and ingestion.

- **Health Canada PMRA:**
  - *Short- and intermediate-term dermal exposure*. An overall NOAEL of 3 mg/kg bw/day from several repeat-dose (21–28-day) dermal toxicity study in rats was selected, based on spasms and tremors at 4 mg/kg bw/day and mortality in female rats at 12 mg/kg bw/day. The target margin of exposure (MOE) is 300; 10-fold for interspecies and 10-fold for intraspecies variations, with an additional safety factor of 3-fold for potential sensitivity in the young and the lack of a developmental neurotoxicity study in rats. Because a dermal NOAEL was selected, a dermal absorption factor is not required for route-to-route extrapolation.
  - *Inhalation exposure scenarios*. The NOAEL of 0.2 mg/kg bw/day from a 21-day rat inhalation study was chosen for all inhalation exposure scenarios, based on decreased body-weight gain and reduced leucocyte counts at 0.4 mg/kg bw/day. The target MOE is 300, 10-fold for interspecies and 10-fold for intraspecies variations and an additional 3-fold for potential sensitivity in the young and the lack of a developmental neurotoxicity study in rats. There was no apparent increase in toxicity with duration; therefore, an additional safety factor to account for use of a short-term study to extrapolate to a longer term scenario was not required.

- All Agencies accepted NOAELs from the 1-year dietary dog study (Brunk, 1989; NOAEL = 0.57 mg/kg/day) and from the combined chronic/carcinogenicity study in rats (Barnard et al., 1985; NOEL = 0.6 mg/kg/day) for long-term (life time) dietary and dermal exposures. The inter-agency comparison is set out in the following table:

Table 29: NOAEL/LOAEL used by Agency and overseas regulators to estimate AOEL

Comparison of critical NOAEL/LOAEL used for occupational

exposure health benchmarks (mg/kg b.w./day)				
Agency	**Acute**	**Short-term (1–30 Days)**	**Intermediate (Seasonal, 1–6 Months)**	**Long-term (Annual, >6 Months)**
APVMA (1998)		Oral NOEL = 1.92	Oral NOEL = 1.92	
PMRA (2007)		Dermal NOAEL = 3 Inhalation NOEL = 0.2	Dermal NOAEL = 3 Inhalation NOEL = 0.2	Oral NOEL = 0.6 Inhalation NOEL = 0.2
US EPA (2007)	Oral NOAEL = 1.5	Oral LOAEL = 3.7 Inhalation NOEL = 0.2	Oral LOAEL = 3.7 [Inhalation NOEL = 0.2]	Oral NOEL = 0.6 Inhalation - no risk
Cal DPR (2008)	Oral NOEAL = 0.7 Inhalation NOEL = 0.194	Oral NOEL = 0.7 Inhalation NOEL = 0.194	Oral NOEL = 1.18 Inhalation NOEL = 0.194	Oral NOEL = 0.57 Inhalation NOEL = 0.0194
ERMA (2008)		Oral LOAEL = 1.92	Oral LOAEL = 1.92	

Conclusion on AOEL:

4.3.130 The Agency derived an AOEL of 0.0192 mg/kg b.w./day based on the NOAEL of 1.92 mg/kg/day from the 13-week dietary study in rats (Barnard et al., 1985).

Conclusion on ADE:

4.3.131 The Agency bases its Acceptable Daily Exposure (ADE) of 0.006 mg/kg b.w./day based on the NOAEL of 0.6 mg/kg/day from the 1-year dietary dog study (Brunk, 1989) and from the combined chronic/carcinogenicity study in rats (Barnard et al., 1985).

Occupational Exposure and Risk

4.3.132 The work activities for which exposure is estimated are mixing, loading (usually grouped) and application. Exposure of workers entering the spray area after application, for example, to weed the crop (post-application or re-entry activities), are also estimated.

4.3.133 As the Agency has no actual exposure data measured in the field under New Zealand conditions, operator (mixer/loader/applicator) exposures are estimated using the United Kingdom Pesticide Safety Directorate's (UK PSD) interpretation of the German BBA Model.[18] The derived values consider both dermal and inhalation exposure routes using the geometric mean model.

[18] Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products. Biologische Bundesanstalt für Land- und Forstwirtschaft, Bundesgesundheitsamt, und Industrieverband Agrar e.V. ISBN 3489-27700-7. 1992; http://www.pesticides.gov.uk/index.htm.

4.3.134 To estimate risks to users and workers entering the sprayed areas post-application, exposures are predicted under likely use patterns, taking into consideration the time worked, use of mitigation (personal protective equipment, PPE), and for post-application, any time before re-entry.

4.3.135 Estimated exposures based on models are compared to relevant health hazard benchmarks (AOELs) derived above that have been derived from appropriate NOAEL described in the toxicology data package on the substance. The NOAELs are selected to match the duration of exposure (acute for intermittent daily exposure or subchronic for seasonal exposures), the target adult population, and route of exposure (dermal or inhalation). Factors are applied to the NOAELs to account for the uncertainties involved in extrapolating data derived from animal test models to humans. A NOAEL of less uncertainty may be preferred over another that appears a better match, for example in terms of duration, but has greater uncertainties.

Exposure of operators to spray:

4.3.136 For occupational situations the main routes of exposure are assumed to be through the skin (dermal) or by inhalation. Ingestion of pesticide is not considered in occupational estimates, as it should not occur in a trained work force.

4.3.137 The BBA model calculates total systemic exposure or the total absorbed dose from both routes. The default assumption is that 100% of the inhaled material is absorbed, and for endosulfan this default value is used. However, estimation of dermal absorption (skin penetration) is more complex and, indeed, overseas jurisdictions have applied different dermal absorption factors for endosulfan.

4.3.138 The Agency notes that all four recent risk assessments for endosulfan (APVMA, 2005; US EPA, 2002 & 2007; PMRA, 2007; and Cal DPR, 2008) appear to use the same *in-vivo* rat studies as the basis for their dermal absorption factors. The US EPA (2007), PMRA (2007) and Cal DPR (2008) derived dermal absorption factors of 45%, 47% and 47.3% based on the studies of endosulfan penetration through rat skin of Craine, 1986 and 1988 [as quoted in US EPA (2007) and Cal DPR (2008)]. Also, the APVMA , also using Craine, 1986 and 1988 [as quoted in APVMA (1998 & 2005)] derived dermal absorption factors for rat skin of 46% for diluted spray mix and 20% for concentrate.

"In the second rat study (Craine, 1988), radiolabelled endosulfan in an EC formulation was applied to the skin (10.8 cm^2) of female rats (mean bw 240 g) at 0.09, 0.98 and 10.98 mg/kg (equal to 22, 235, 2640 µg/animal or 2.0, 22, 244 µg/cm^2). The test compound was then washed off after 10 hours. Animals were sacrificed at 24, 48, 72 hours or 7 days after the dose application to determine absorption and distribution of endosulfan. Mean recovery of radiolabel ranged between 96 – 108%. Initial absorption into the skin was related inversely to dose, with skin washings removing 30, 45 and 66% of the applied radiolabel at 2, 22 and 244 µg/cm^2, respectively. Movement through the skin was slow. In the 2, 22 and 244 µg/cm^2 groups

respectively, penetration of radiolabel reached 22, 16 and 4% of the applied dose by 24 hours, when 41, 39 and 33% of applied radiolabel was still bound to the skin. At 48 hours, penetration of radiolabel had attained 35, 36 and 11% in the three respective groups. Penetration attained 45, 46 and 20% by 7 days, by which time only 1 – 2% of the dose remained bound to the skin." (APVMA Vol2, 2005)

4.3.139 The Agency concurs that the *in vivo* rat dermal absorption data appears sound, and that available data indicates that concentrated material is relatively less well absorbed through the skin than spray mixes and that, human skin is less permeable to endosulfan than rat skin.

4.3.140 The APVMA used *in vitro* study data (Noctor and John, 1995 as quoted in APVMA, 1998 and Davies, 2002 as quoted in APVMA, 2005) that compared the rates of endosulfan penetration though rat and human skin samples. The data from Davies (2002) was applied to the *in vivo* rat dermal absorption factors (Craine 1998) to derive dermal absorption factors for humans of 0.5% for concentrates i.e. mixing/loading, and 1.52% for spraying and re-entry activities used in the 2005 APVMA OHS risk assessment.

"From further consideration of these submitted studies ……., it is apparent that endosulfan is less well absorbed across rat skin in vivo than in vitro. Under identical experimental conditions, human epidermis is at least 30-fold less permeable to endosulfan than rat epidermis.

In light of these new findings the previous worker exposure estimates where dermal absorption figures were derived from animal experimentation results and applied to human exposure scenarios were revisited. A dermal absorption factor of 0.5% for concentrates i.e. mixing/loading, and 1.52% for spraying and re-entry activities has been used in the OHS risk assessment." *(APVMA Vol2, 2005)*

4.3.141 Derivation of the dermal absorption factors values is described:

"Consistent with the EC Guidance Document on Dermal Absorption, factors for endosulfan can be calculated by adjusting the rat in vivo absorption values by the ratio of the human to the rat in vitro absorption. The dermal absorption factor for concentrate exposure will be 20% x 0.025 = 0.50%, while the factor for exposure to spray mixture will be 46% x 0.033 = 1.52%." (APVMA Vol2, 2005)
[Where 20% and 46% were the penetration rates through rat skin for the concentrate and spray mix; and, 0.025 and 0.033 express the difference in penetration rate between rat and human skin.]

4.3.142 The Agency considered whether or not to follow the same approach as the APVMA and noted that the US EPA had not taken this approach.

4.3.143 Whilst the US EPA was aware of the study by Noctor and John, 1995 (US EPA, 2002), the study by Davies (2002) does appear not to have been available to them or the Cal DPR for their assessments (Sheryl Beauvais

pers. comm. 2008). However, according to a draft protocol for deriving dermal absorption factors currently being adopted by US EPA, PMRA and Cal DPR, the available *in vitro* studies would not be adequate to elaborate a human absorption factor from the rat data (Sheryl Beauvais *pers. comm.* 2008).

4.3.144 After obtaining a copy of Davies, 2002, the Agency had this reviewed by Dr M Edwards PhD of Toxicology Consulting Limited. Dr Edwards' report is attached as confidential Appendix K. In the light of Dr Edwards' report, the Agency concluded that the Davies 2002 study does not provide a firm basis for using a greatly reduced figure for the proportion of endosulfan absorption in humans, for the following reasons:

- The study does not include results for other test substances of similar lipophilicity to endosulfan.
- The source of human skin used in the experiment is not given, which raises questions around the relevance for persons exposed.
- The comparison of data for the absorption of endosulfan in rats *in vitro* (based on Davies, 2002) and *in vivo* (based on Craine, 1998) shows a marked difference, which calls into question the validity of the *in vitro* results.
- The study assumes that endosulfan retained on the epidermis should not be included as absorbed material, in contrast to the OECD guidelines on this issue (OECD, 2004), although the Agency notes that this does not appear to greatly change the outcome.

Therefore, the Agency used 46% as the proportion of endosulfan in diluted spray that would be absorbed from exposed skin and 20% for the endosulfan concentrate which is based on Craine.

Activity Scenarios

4.3.145 In all scenarios, exposure to a liquid, 350 g a.i./l formulation, by a 70 kg operator with dermal absorption of 20% for concentrates (mixing/loading), and 46% for spraying is modelled:

Table 30: Scenarios considered in the operator risk assessment

Scenario		Application		
		Equipment	Rate (g a.i./ha)	Work rate (ha/day)*
1	Label use	Tractor mounted/trailed boom sprayer: hydraulic nozzles	700	20
2	Turf (off-label)		2100	
3	Citrus (off-label)	Boom sprayer: air-assisted sprayer (air-blast)	1300	8
4	Hand-held (off-label)	Hand-held sprayer: hydraulic nozzles, outdoors high level target	700	1
5	Greenhouse	Remote trolley sprayers or low-volume misters	700	(semi-) automated

* In all scenarios the default value for the German BBA model is used in the absence of specific work rate data in the New Zealand context.

4.3.146 For the first of the four activities, 11 levels of PPE are considered, and 6 for the remaining three. Note that the greenhouse application is by remote or automated sprayers so that workers are normally involved only in mixing and loading at rates already modelled in scenario 1.

Operator exposure

4.3.147 As can be seen in Table 31 below, in scenario 1 (Endosulfan 350 EC at maximum label rate), gloves at mixing/loading and application make a large impact on estimated exposures, as does adding overalls, boots and head gear. The improvement in using a hood and visor over a broad-rimmed hat is less marked in terms of estimated exposures, but may be significant for eye protection and comfort.

4.3.148 The use of A1P2 respirators, instead of no RPE during mixing/loading appears to have little impact on the calculated absorbed dose of endosulfan. However, the A1P2 should be protective where solvent vapours result from the other excipients.

4.3.149 The use of A1P2 respirators instead of FFP2SL or P2 has little impact on the calculated inhalation absorbed dose of endosulfan. However, the A1P2 should be more protective where solvent vapours result from the other excipients.

Table 31: Operator exposure estimates

Occupational Exposure Estimates [a] Scenario (1): Endosulfan 350 EC at maximum label rate tractor mounted/trailed boom sprayer: hydraulic nozzles			
	Dermal absorbed dose (mg/day) [b]	**Inhalation absorbed dose (mg/day) [c]**	**Total operator exposure (mg/kg b.w./day)[d]**
Mixing/loading: A1P2 + gloves Application: A1P2 + hood/visor + overalls + boots + gloves	0.067 [e] 0.555 [f]	0.00017 [e] 0.00028 [f]	0.0089
Mixing/loading: FFP2SL or P2 + gloves Application: FFP2SL or P2 + hood/visor + overalls + boots + gloves	0.067 0.555	0.00042 0.00028	0.0089
Mixing/loading: A1P2 + gloves Application: A1P2 + hat + overalls + boots + gloves	0.067 0.69	0.00017 0.00028	0.011
Mixing/loading: FFP2SL or P2 + gloves Application: FFP2SL or P2 + hat + overalls + boots + gloves	0.067 0.694	0.00042 0.00028	0.011
Mixing/loading: gloves Application: hood/visor + overalls + boots + gloves	0.067 0.559	0.0084 0.014	0.0093
Mixing/loading: gloves Application: hat + overalls + boots + gloves	0.067 0.733	0.0084 0.014	0.012
Mixing/loading: gloves Application: gloves	0.067 10.7	0.0084 0.014	0.15
Mixing/loading: no PPE Application: gloves	6.7 10.7	0.0084 0.014	0.25
Mixing/loading: A1P2 + gloves Application: no PPE	0.067 13.1	0.00017 0.014	0.19
Mixing/loading: gloves Application: no PPE	0.067 13.1	0.0084 0.014	0.19
Mixing/loading: no PPE Application: no PPE	6.7 13.1	0.0084 0.014	0.28

[a] UK PSD interpretation of the German BBA Model – geometric mean

[b] Assumes 20% dermal absorption for concentrates i.e. mixing/loading, 46% for spraying

[c] Assumes 100% inhalation absorption

[d] Assumes 70kg body weight, mixing/loading/application

[e] Mixing/Loading

[f] Application

Occupational Exposure Estimates [a] Scenario (2): Endosulfan 350 EC on turf at 2.1kg a.i./ha tractor mounted/trailed boom sprayer: hydraulic nozzles			
	Dermal absorbed dose (mg/day) [b]	**Inhalation absorbed dose (mg/day) [c]**	**Total operator exposure (mg/kg b.w./day)[d]**
Mixing/loading: A1P2 + gloves Application: A1P2 + hood/visor + overalls + boots + gloves	0.202 [e] 1.7 [f]	0.0005 [e] 0.0008 [f]	0.027
Mixing/loading: gloves Application: hood/visor + overalls + boots + gloves	0.202 1.7	0.025 0.042	0.028
Mixing/loading: gloves Application: gloves	0.202 32.2	0.025 0.042	0.46
Mixing/loading: no PPE Application: gloves	20.2 32.2	0.025 0.042	0.75
Mixing/loading: gloves Application: no PPE	0.202 39.4	0.025 0.042	0.57
Mixing/loading: no PPE Application: no PPE	20.2 39.4	0.025 0.042	0.85

[a] UK PSD interpretation of the German BBA Model – geometric mean

[b] Assumes 20% dermal absorption for concentrates i.e. mixing/loading, 46% for spraying

[c] Assumes 100% inhalation absorption

[d] Assumes 70kg body weight, mixing/loading/application

[e] Mixing/Loading

[f] Application

Occupational Exposure Estimates [a] Scenario (3): Endosulfan 350 EC on citrus at 1.3kg a.i./ha tractor mounted/trailed boom sprayer: air-assisted sprayer			
	Dermal absorbed dose (mg/day) [b]	**Inhalation absorbed dose (mg/day) [c]**	**Total operator exposure (mg/kg b.w./day)[d]**
Mixing/loading: A1P2 + gloves Application: A1P2 + hood/visor + overalls + boots + gloves	0.050 [e] 2.6 [f]	0.00013 [e] 0.0038 [f]	0.038
Mixing/loading: gloves Application: hood/visor + overalls + boots + gloves	0.050 2.6	0.0063 0.19	0.041
Mixing/loading: gloves Application: gloves	0.050 52.2	0.0063 0.19	0.75
Mixing/loading: no PPE Application: gloves	5.04 52.2	0.0063 0.19	0.82
Mixing/loading: gloves Application: no PPE	0.050 55.6	0.0063 0.19	0.80
Mixing/loading: no PPE Application: no PPE	5.04 55.6	0.0063 0.19	0.87

[a]	UK PSD interpretation of the German BBA Model – geometric mean
[b]	Assumes 20% dermal absorption for concentrates i.e. mixing/loading, 46% for spraying
[c]	Assumes 100% inhalation absorption
[d]	Assumes 70kg body weight, mixing/loading/application
[e]	Mixing/Loading
[f]	Application

Occupational Exposure Estimates [a] **Scenario (4): Endosulfan 350 EC off-label at 0.7kg a.i./ha** **Hand-held; hydraulic nozzles; outdoors, high level target**			
	Dermal absorbed dose (mg/day) [b]	**Inhalation absorbed dose (mg/day) [c]**	**Total operator exposure (mg/kg b.w./day)[d]**
Mixing/loading: A1P2 + gloves Application: A1P2 + hood/visor + overalls + boots + gloves	0.287 [e] 0.50 [f]	0.0007 [e] 0.0042 [f]	0.011
Mixing/loading: gloves Application: hood/visor + overalls + boots + gloves	0.287 0.514	0.035 0.21	0.015
Mixing/loading: gloves Application: gloves	0.287 9.6	0.035 0.21	0.15
Mixing/loading: no PPE Application: gloves	28.7 9.6	0.035 0.21	0.55
Mixing/loading: gloves Application: no PPE	0.287 13.0	0.035 0.21	0.19
Mixing/loading: no PPE Application: no PPE	28.7 13.0	0.035 0.21	0.60
[a] UK PSD interpretation of the German BBA Model – geometric mean [b] Assumes 20% dermal absorption for concentrates i.e. mixing/loading, 46% for spraying [c] Assumes 100% inhalation absorption [d] Assumes 70kg body weight, mixing/loading/application [e] Mixing/Loading [f] Application			

4.3.150 Comparison of exposure estimates between reviews carried out by other agencies has not been performed due to the different models employed, the inclusion/exclusion of measured data, the PPE requirements in each jurisdiction, and the use patterns/label claims in each case.

Risk Quotients:

4.3.151 To assess occupational risks the Agency has divided the estimated exposure values by the AOEL to derive a risk quotient (RQ) for each exposure scenario.

$$RQ = \frac{\text{Estimated Occupational Exposure}}{\text{AOEL}}$$

A RQ>1 indicates the likelihood of a high risk to those exposed. The results for each scenario are set out in Table 32 below.

Table 32: Results of operator risk assessment

Risk Quotient (RQ) and Acceptable Operator Exposure Level (AOEL) Scenario (1): Endosulfan 350 EC at maximum label rate			
	Total operator exposure (mg/kg b.w./day) [a]	**AOEL (mg/kg b.w./day) [b]**	**RQ [c]**
Gloves at mixing / loading +A1P2 resp+gloves+ hood/visor+overalls+ boots at application	0.0089	0.0192	0.46
Gloves at mixing / loading +Gloves+ hood/visor+overalls +boots at application	0.0093		0.48
Gloves at mixing / loading / application	0.15		8
Gloves at application	0.25		13
Gloves at mixing / loading	0.19		10
No PPE	0.28		15

[a] UK PSD interpretation of the German BBA Model – geometric mean

[b] From NOAEL = 1.92 mg/kg b w/day (13-week dietary study in rats; Barnard et al., 1985); uncertainty factors 10x & 10x; 100% oral absorption factor

[c] RQ = Total Estimated Occupational Exposure / AOEL

[d] RQ > 1 indicates the likelihood of an unacceptable risk to those exposed

Risk Quotient (RQ) and Acceptable Operator Exposure Level (AOEL) Scenario (2): Endosulfan 350 EC on turf at 2.1kg a.i./ha			
	Total operator exposure (mg/kg b.w./day) [a]	**AOEL (mg/kg b.w./day) [b]**	**RQ [c]**
Gloves at mixing / loading +A1P2 resp+gloves+ hood/visor+overalls+ boots at application	0.027	0.0192	1.4
Gloves at mixing / loading +Gloves+ hood/visor + overalls + boots at application	0.028		1.5
Gloves at mixing / loading / application	0.46		24
Gloves at application	0.75		39
Gloves at mixing / loading	0.57		30
No PPE	0.85		44
a UK PSD interpretation of the German BBA Model – geometric mean b From NOAEL = 1.92 mg/kg b w/day (13-week dietary study in rats; Barnard et al., 1985); uncertainty factors 10x & 10x; 100% oral absorption factor c RQ = Total Estimated Occupational Exposure / AOEL d RQ > 1 indicates the likelihood of an unacceptable risk to those exposed			

Risk Quotient (RQ) and Acceptable Operator Exposure Level (AOEL) Scenario (3): Endosulfan 350 EC on citrus at 1.3kg a.i./ha			
	Total operator exposure (mg/kg b.w./day) [a]	**AOEL (mg/kg b.w./day) [b]**	**RQ [c]**
Gloves at mixing / loading +A1P2 resp+gloves+ hood/visor+overalls+ boots at application	0.038	0.0192	2
Gloves at mixing / loading +Gloves+ hood/visor + overalls +boots at application	0.041		2
Gloves at mixing / loading / application	0.75		39
Gloves at application	0.82		43
Gloves at mixing / loading	0.80		42
No PPE	0.87		45
[a] UK PSD interpretation of the German BBA Model – geometric mean [b] From NOAEL = 1.92 mg/kg b w/day (13-week dietary study in rats; Barnard et al., 1985); uncertainty factors 10x & 10x; 100% oral absorption factor [c] RQ = Total Estimated Occupational Exposure / AOEL [d] RQ > 1 indicates the likelihood of an unacceptable risk to those exposed			

Risk Quotient (RQ) and Acceptable Operator Exposure Level (AOEL) Scenario (4): Endosulfan 350 EC at maximum label rate – handheld			
	Total operator exposure (mg/kg b.w./day) [a]	**AOEL (mg/kg b.w./day) [b]**	**RQ [c]**
Gloves at mixing / loading +A1P2 resp+gloves+ hood/visor+overalls+ boots at application	0.011	0.0192	0.57
Gloves at mixing / loading +Gloves+ hood/visor +overalls +boots at application	0.015		0.78
Gloves at mixing / loading / application	0.15		8
Gloves at application	0.55		29
Gloves at mixing / loading	0.19		10
No PPE	0.60		31

[a] UK PSD interpretation of the German BBA Model – geometric mean

[b] From NOAEL = 1.92 mg/kg b w/day (13-week dietary study in rats; Barnard et al., 1985); uncertainty factors 10x & 10x; 100% oral absorption factor

[c] RQ = Total Estimated Occupational Exposure / AOEL

[d] RQ > 1 indicates the likelihood of an unacceptable risk to those exposed

Conclusions on Risk Quotient (RQ) and Occupational Exposure Estimates for Mixer/Loaders and Applicators:

4.3.152 Only in scenarios 1 and 4 where full PPE is used (gloves at mixing/loading + gloves + hood/visor + overalls + boots at application) with or without respirators (A1P2), were the calculated Risk Quotients (RQ) less than 1. The RQs for ground-boom applications and air-blast applications to citrus were unacceptable even with full PPE.

4.3.153 Gloves should be used for mixing/loading for greenhouse applications (Total Mixer/Loader Exposure = 0.0011mg/kg bw/day; RQ = 0.06), where applications are done remotely using automated systems.

Occupational post-application or re-entry worker exposures

4.3.154 The routes of exposure during post-application activities are analogous to those for the operator, i.e. dermal and inhalation. However, the sources are different: foliage, soil and dust may contribute as treated surfaces cause pesticide residues to be transferred to the skin. Oral exposure may also occur as a consequence of dermal exposure, i.e. through hand to mouth activities, but is usually ignored except for children.

4.3.155 Most maintenance activities include frequent contact with the foliage of the crop. Therefore, dermal exposure is considered to be the most important exposure route during these re-entry activities. The amount of resulting

exposure (for a certain activity) depends on the amount of residue on foliage, the intensity of contact with the foliage and the duration of contact. Similarly, the dermal route is also expected to be the significant route of exposure for members of the public entering treated crops (for example, for pick-your-own).

4.3.156 Inhalation exposure may potentially occur from residual vapour and airborne aerosols. Movement of the crop may also result in inhalation exposure to aerosol/vapour as well as dust during re-entry activities. For outdoor situations there will be more rapid dissipation of vapour and aerosols, leading to lower inhalation potential than from indoor treatments, such as those made to protected crops grown in glasshouses.

4.3.157 Most re-entry activities are not expected to result in pesticide exposure throughout the year, as endosulfan is not applied all year in all crops, and many activities are performed only seasonally.

4.3.158 For re-entry exposure the extent of dermal absorption has been assessed by APVMA (2005) to be closely similar to that which has been estimated for endosulfan in diluted spray mixture, rather than the extent of absorption from exposure to concentrated formulations. Noting this view, the Agency has applied a dermal absorption factor of 46% for re-entry exposure assessment.

4.3.159 The Agency has used the UK PSD Guidance for Post-Application (Re-Entry Worker) Exposure Assessment (2008a) to model exposures for some New Zealand activities.[19]

Dermal Exposures:

Dislodgeable foliar residue (DFR)

4.3.160 The amount of residue on foliage depends on several factors, for example, the application rate, targeting and retention of spray, crop type and the amount of foliage (leaf area index). Moreover, dissipation of residues on crop foliage over time depends on the physical and chemical properties of the applied active substance as well as on environmental conditions. Where experimentally determined dislodgeable foliar residue data are not available, a worse case assessment of the initial DFR (DFR0), in a first tier assessment, assumes 3 micrograms of active substance/square centimetre of foliage/per kg a.s. applied/hectare (UK PSD, 2008a).

Transfer coefficient (TC)

4.3.161 The transfer of residues from the plant surface to the clothes or skin of the worker can be regarded as more or less independent of the kind of product applied and the level of exposure will depend on the intensity and duration of contact with the foliage. This is also determined by the nature and duration of the activity during re-entry. Therefore, it is possible to group

[19] http://www.pesticides.gov.uk/approvals.asp?id=2422&link=%2Fuploadedfiles%2FWeb%5FAssets%2FPSD%2FRe%2Dentry%2520worker%2520guidance%5Ffinal%2520version%2Epdf

various crop habitats and re-entry activities. The EUROPOEM Group recommended the following **indicative** TC values for potential dermal exposure for four different harvesting scenarios. These TC values assume harvesting is performed with bare hands and dermal exposure to the body is reduced ten fold by clothing worn by the worker.

Crop	Nature of task	Transfer Coefficient (cm^2 / hr)
Vegetables	Reach / Pick	2500
Fruits (from trees)	Search / Reach / Rick	4500
Berries	Reach / Pick	3000
Ornamentals	Cut / Sort / Bundle / Carry	5000

4.3.162 For other re-entry scenarios, TC data may be extrapolated where the scenarios are considered to be comparable, i.e. the intensity and duration of contact with the foliage is similar (UK PSD, 2008a).

Inhalation Exposures:

4.3.163 Although in many cases inhalation exposure will be less significant for the exposure assessment than dermal exposure, the EUROPOEM Group have proposed task-specific factors that may be used for the first tier of an exposure assessment relating to harvesting ornamentals and to the re-entry of greenhouses approximately 8-16 hours after treatment. Inhalation exposure for this re-entry scenario may be predicted from the following model (algorithm) (UK PSD, 2008a):

mg a.s./hr inhaled = kg/a.s./ha applied x Task Specific Factor

4.3.168 The **indicative** Task Specific Factors proposed for the first tier of the exposure assessment are:

- 0.1 for cutting ornamentals;
- 0.01 for sorting and bundling of ornamentals;
- 0.03 for re-entering greenhouses after low-volume-mist application;
- 0.15 for re-entering greenhouses after roof fogger application.

4.3.169 This approach may be used for non-volatile pesticides, where levels of inhalation exposure (vapour and dust) would be expected to be low in comparison with dermal exposure (UK PSD, 2008a).

4.3.170 The New Zealand representative re-entry activities modelled are:

- hand-harvesting citrus: dermal exposure;
- hand-harvesting berries: dermal exposure;
- cutting ornamentals: dermal and inhalation exposures; and,
- hand-harvesting greenhouse tomatoes: dermal and inhalation exposures.

Re-entry scenarios

Re-entry by a worker to hand-harvest citrus: dermal exposure

4.3.171 Assuming an application of 375 ml endosulfan 350 EC in 100 litres water (1.30 mg/ml) that may be applied twice, therefore the maximum total dose is 2.6 kg a.s./ha.

4.3.172 This estimate assumes no dissipation of residues between treatments.

4.3.173 A working day of 8 hours is assumed to account for hand-harvesting.

4.3.174 For the transfer of residues from foliage to the clothes or skin of a worker, a TC value of 4500 cm2/hr is used for hand-harvesting citrus, as recommended by the EUROPOEM Group.

4.3.175 A DFR value of 3 µg/cm2 per kg as/ha applied is assumed.

4.3.176 Predicted exposure for this scenario based on the PSD equation (by adding a factor for dermal exposure and dividing by the worker's body weight) gives:

$$D = DFR \times TC \times \% \text{ absorbed} \times WR \times AR \times P / BW$$

Where:

D = Dermal Exposure [µg a.s./person*d]

DFR = Dislodgeable Foliar Residue per kg a.s./ha = 3.0 µg a.s./cm² per kg a.s./ha

TC = Transfer Coefficient [cm²/person/h] = 4500 [cm²/person/h]

% absorbed = percentage dermal absorption (46%)

WR = Work Rate [8 hours/day]

AR = Application Rate [2.6 kg a.s./ha]

P = clothing such as a long sleeved shirt is taken into account

BW = bodyweight (60 kg)

$$D = \frac{3 \times 4500 \times 0.46 \times 8 \times 2.6 \times 1}{60}$$

4.3.177 Dermal Exposure (D) is 2153 µg a.s./kg bw/day or 2.153 mg a.s./kg bw/day. This is equivalent to an estimated RQ of >10.

Re-entry by a worker to hand-harvest berries: dermal exposure

4.3.178 Assuming an application of 200 ml endosulfan 350 EC in 100 litres water (0.70 mg/ml) that may be applied twice, therefore the maximum total dose is 1.4 kg a.s./ha.

4.3.179 This estimate assumes no dissipation of residues between treatments.

4.3.180 A working day of 8 hours is assumed to account for hand-harvesting.

4.3.181 For the transfer of residues from foliage to the clothes or skin of a worker, a TC value of 3000 cm2/hr is used for hand-harvesting berries, as recommended by the EUROPOEM Group. Note that for hand-harvesting vegetables a lower TC value of 2500 cm2/hr is recommended by the EUROPOEM Group (UK PSD, 2008a).

4.3.182 A DFR value of 3 µg/cm2 per kg as/ha applied is assumed.

4.3.183 Predicted exposure for this scenario is thus (using different TC value and application rates from those above for citrus):

$$D = DFR \times TC \times \% \text{ absorbed} \times WR \times AR \times P / BW$$

Where:

D = Dermal Exposure [µg a.s./person*d]

DFR = Dislodgeable Foliar Residue per kg a.s./ha = 3.0 µg a.s./cm² per kg a.s./ha

TC = Transfer Coefficient [cm²/person/h] = 3000 [cm²/person/h]

% absorbed = percentage dermal absorption (46%)

WR = Work Rate [8 hours/day]

AR = Application Rate [1.4 kg a.s./ha]

P = clothing such as a long sleeved shirt is taken into account

BW = bodyweight (60 kg)

$$D = \frac{3 \times 3000 \times 0.46 \times 8 \times 1.4 \times 1}{60}$$

4.3.184 Dermal Exposure (D) is 773 µg a.s./kg bw/day or 0.773 mg a.s./kg bw/day. This is equivalent to an estimated RQ of >10.

Re-entry by a worker to cut ornamentals: dermal exposure

4.3.185 Assuming an application of 200 ml endosulfan 350 EC in 100 litres water (0.70 mg/ml) that may be applied twice, therefore the maximum total dose is 1.4 kg a.s./ha.

4.3.186 This estimate assumes no dissipation of residues between treatments.

4.3.187 A working day of 8 hours is assumed to account for hand-harvesting.

4.3.188 For the transfer of residues from foliage to the clothes or skin of a worker, a TC value of 5000 cm2/hr is used for cutting, sorting, bundling or carrying ornamentals, as recommended by the EUROPOEM Group (UK PSD, 2008a).

4.3.189 A DFR value of 3 µg/cm2 per kg as/ha applied is assumed.

4.3.190 Predicted exposure for this scenario is thus:

$$D = DFR \times TC \times \% \text{ absorbed} \times WR \times AR \times P / BW$$

Where:

D = Dermal Exposure [µg a.s./person*d]

DFR = Dislodgeable Foliar Residue per kg a.s./ha = 3.0 µg a.s./cm² per kg a.s./ha

TC = Transfer Coefficient [cm²/person/h] = 5000 [cm²/person/h]

% absorbed = percentage dermal absorption (46%)

WR = Work Rate [8 hours/day]

AR = Application Rate [1.4 kg a.s./ha]

P = clothing such as a long sleeved shirt is taken into account

BW = bodyweight (60 kg)

$$D = \frac{3 \times 5000 \times 0.46 \times 8 \times 1.4 \times 1}{60}$$

4.3.191 Dermal Exposure (D) is 1288 µg a.s./kg bw/day or 1.288 mg a.s./kg bw/day. This is equivalent to an estimated RQ of >10.

Re-entry by a worker to cut ornamentals: inhalation exposure

4.3.192 Assuming an application of 200 ml endosulfan 350 EC in 100 litres water (0.70 mg/ml) that may be applied twice, but this estimate assumes dissipation of residues between treatments. Predicted exposure is calculated thus:

mg a.s./hr inhaled = kg/a.s./ha applied x Task Specific Factor

Where:

indicative Task Specific Factors = 0.1 for cutting ornamentals;

WR = Work Rate [8 hours/day]

AR = Application Rate [0.7 kg a.s./ha]

BW = bodyweight (60 kg)

$$\text{mg a.s./hr inhaled} = 0.7 \times 0.1 = 0.07 \text{ mg a.s./hr}$$

$$\text{Inhalation Exposure (I)} = \text{mg a.s./hr inhaled} \times WR / BW$$

$$I = (0.07 \times 8) / 60 = 0.0093 \text{ mg/kg bw/day}$$

4.3.193 Inhalation Exposure (I) is 0.0093 mg a.s./kg bw/day. This is equivalent to 49% of the AOEL of 0.0192 mg/kg bw/day. The combined dermal and inhalation exposure gives an RQ of >10.

Re-entry by a worker to hand-harvest greenhouse tomatoes: dermal exposure

4.3.194 Assuming an application of 200 ml endosulfan 350 EC in 100 litres water (0.70 mg/ml) that may be applied twice, therefore the maximum total dose is 1.4 kg a.s./ha.

4.3.195 This estimate assumes no dissipation of residues between treatments.

4.3.196 A working day of 8 hours is assumed to account for hand-harvesting.

4.3.197 For the transfer of residues from foliage to the clothes or skin of a worker, a TC value of 5000 cm2/hr is used for cutting, sorting, bundling or carrying ornamentals, as recommended by the EUROPOEM Group (UK PSD, 2008a).

4.3.198 A DFR value of 3 µg/cm2 per kg as/ha applied is assumed.

4.3.199 Predicted exposure for this scenario is thus:

$$D = DFR \times TC \times \% \text{ absorbed} \times WR \times AR \times P / BW$$

Where:

D = Dermal Exposure [µg a.s./person*d]

DFR = Dislodgeable Foliar Residue per kg a.s./ha = 3.0 µg a.s./cm² per kg a.s./ha

TC = Transfer Coefficient [cm²/person/h] = 5000 [cm²/person/h]

% absorbed = percentage dermal absorption (46%)

WR = Work Rate [8 hours/day]

AR = Application Rate [1.4 kg a.s./ha]

P = clothing such as a long sleeved shirt is taken into account

BW = bodyweight (60 kg)

$$D = \frac{3 \times 5000 \times 0.46 \times 8 \times 1.4 \times 1}{60}$$

4.3.200 Dermal Exposure (D) is 1288 µg a.s./kg bw/day or 1.288 mg a.s./kg bw/day. This is equivalent to an estimated RQ of >10.

Re-entry by a worker to hand-harvest greenhouse crops: inhalation exposure after roof fogger application.

4.3.201 Assuming an application of 200 ml endosulfan 350 EC in 100 litres water (0.70 mg/ml) that may be applied twice, but this estimate assumes dissipation of residues between treatments. Re-entry of greenhouses is assumed to be approximately 8-16 hours after treatment.

mg a.s./hr inhaled = kg/a.s./ha applied x Task Specific Factor

Where:

indicative Task Specific Factors = 0.15 after roof fogger application;
WR = Work Rate [8 hours/day]
AR = Application Rate [0.7 kg a.s./ha]
BW = bodyweight (60 kg)

mg a.s./hr inhaled = 0.7 x 0.15 = 0.105 mg a.s./hr

Inhalation Exposure (I) = mg a.s./hr inhaled x WR / BW

I = (1.05 x 8) / 60 = 0.014 mg/kg bw/day

4.3.202 Inhalation Exposure (I) is 0.014 mg a.s./kg bw/day. This is equivalent to 73% of the AOEL of 0.0192 mg/kg bw/day. The combined dermal and inhalation exposure gives an RQ of >10.

Summary of re-entry worker exposures in some representative activities:

Table 33: Re-entry worker exposures

Re-entry worker exposure estimates compared to AOEL[a]		
	Estimated Exposure (mg/kg bw/day)	**Predicted RQ**
Hand-harvesting citrus [b]: dermal exposure	2.153	>10
Hand-harvest berries [c]: dermal exposure	0.773	>10
Cutting ornamentals [d]: dermal exposure inhalation exposure	1.288 0.0093	>10 0.49
Hand-harvesting greenhouse tomatoes [e]: dermal exposure inhalation exposure	1.288 0.014	>10 0.73

[a] AOEL = 0.0192 mg/kg bw/day

[b] field application rate, 1.3 kg a.i./ha x 2 applications

[c] field application rate, 0.7 kg a.i./ha x 2 applications

[d] field application rate, 0.7 kg a.i./ha x 2 applications: but only single rate considered for inhalation exposure

[e] field application rate, 0.7 kg a.i./ha x 2 applications: but only single rate considered for inhalation exposure

Conclusions on re-entry worker exposure estimates in some representative New Zealand activities:

4.3.203 Re-entry worker exposure estimates for some representative New Zealand occupational activities were modelled using the UK PSD Guidance for Post-Application (Re-Entry Worker) Exposure Assessment (2008a).

4.3.204 In each scenario the estimated dermal exposures exceeded the AOEL.

4.3.205 The models did assume re-entry as soon as the spray had dried; no dissipation of residues between treatments; the largest Task Specific Factors; and, the UK PSD default values. The Agency does not currently have the information necessary to refine these exposure estimates.

Bystander exposure

Introduction

4.3.206 The main potential source of exposure to the general public (bystander or resident) from endosulfan (other than via food residues) is via spray drift. Bystander exposures would be intermittent in comparison to exposure of workers, who are handling the pesticide throughout the application. In addition, spray densities, and hence exposure levels drop off with distance from spraying operations.

4.3.207 The Agency notes that any potential bystanders will not be directly handling the substance, and they will not be wearing PPE.

4.3.208 No New Zealand monitoring studies of airborne endosulfan at application sites are available to estimate possible public exposure.

4.3.209 UK PSD Bystander Exposure Guidance Document (2008b[20]) gives models for estimating bystander exposure in three circumstances:

- Exposure from spray drift at the time of application;
- Exposure from inhalation of pesticide which volatilises from the crop or soil surface after the application has been made; and
- Exposure through contact with spray drift contaminated surfaces.

4.3.210 The Agency has applied these models to three potential New Zealand use patterns:

- Broadcast air assisted and knapsack sprayers – Orchard application: to simulate use in citrus (noting that any knapsack sprayer use is likely to produce no worse exposure than that predicted for air-blast application);
- Field crop (boom) sprayers: to simulate turf application; and,
- Field crop (boom) sprayers: to simulate label uses:

Exposure from spray drift at the time of application

4.3.211 The levels of spray drift deposited on the body of a bystander/ resident and that which may be in the breathing zone can be estimated. From this the amount of active substance available for dermal absorption and which may be inhaled can be calculated. It should be assumed that no action is taken to avoid or control exposure and that little clothing is worn. Measurements of bystander exposure during UK field crop spraying and orchard spraying

[20] http://www.pesticides.gov.uk/approvals.asp?id=2428&link=%2Fuploadedfiles%2FWeb%5FAssets%2FPSD%2FBystander%2520exposure%2520guidance%5Ffinal%2520version%2Epdf

applications have been reported by Lloyd and Bell, 1983 and Lloyd et al, 1987 [in UK PSD 2008b].

Broadcast air assisted and knapsack sprayers – orchard application

4.3.212 For orchard sprayer applications the average potential dermal exposure (PDE) for a bystander, positioned 8 metres downwind from the sprayer and the average amount of spray passing through the breathing zone were 3.7 ml spray/person and 0.002 ml spray/person.

"Allowing for a realistic headland of 5m within the orchard, for machinery to operate within, at the boundary of a neighbouring area the level of fallout (from early season applications when leaves are not present) could be equivalent to about 20% of the field rate. The level of deposit would decline away from the orchard boundary to just over 5% at 10 metres[4]. An estimate of the average level of fallout over the whole area from the boundary to 10 metres would be about 10%. This would give a deposit of about 1 µg/cm2/kg applied/ha. Later season fall out levels, would be lower as a result of the crop canopy.

{[4] Rautmann, D; Streloke, M, Winkler, R, (2001): New basic drift values in the authorisation procedure for plant protection products. In Forster, R.; Streloke, M. Workshop on Risk Assessment and Risk Mitigation Measures in the Context of the Authorization of Plant Protection Products (WORMM). Mitt.Biol.Bundesanst.Land-Forstwirtsch. Berlin-Dahlem, Heft 381.} [in UK PSD 2008b]"

4.3.213 Using these data total systemic exposure from spray drift at the time of application can be estimated as follows for broadcast air assisted and knapsack sprayers – Orchard application:

$$\text{Systemic exposure} = (\text{PDE} \times \text{SC} \times \%\ \text{absorbed} + \text{PIE} \times \text{SC} \times 100\%)/\text{BW}$$

Where:

PDE = potential dermal exposure (ml spray)

PIE = potential inhalation exposure (ml spray)

SC = concentration of active substance in spray (1.30 mg a.s./ml spray)

% absorbed = percentage dermal absorption (46%)

BW = bodyweight (60 kg)

$$\frac{(3.7 \times 1.30 \times 0.46) + (0.002 \times 1.30 \times 1.00)}{60} = 0.037 \text{ mg/kg bw/day}$$

4.3.214 Assuming an application of 375 ml endosulfan 350 EC in 100 litres water (1.30 mg/ml), no protection from clothing and 100% inhalation, retention and absorption of potential inhalation exposure (PIE), the estimated bystander exposure is 0.037 mg/kg bw. This is equivalent to an RQ of 1.92

4.3.215 This estimate of exposure for applications from broadcast air assisted sprayers is expected to represent a worse case for equivalent applications of endosulfan 350 EC using knapsack sprayers.

Field crop (boom) sprayers: to simulate turf application

4.3.216 For boom sprayers the average potential dermal exposure (PDE) for a bystander, positioned 8 metres downwind from the sprayer and the average amount of spray passing through the breathing zone were 0.1 ml spray/person and 0.006 ml spray/person, respectively.

"An estimate of bystander exposure has been made by this evaluation, based on a published UK study (Lloyd and Bell, 1983) in which measurements of simulated bystander exposure were made during field crop spraying operations. The average potential dermal exposure for a bystander, positioned 8 metres downwind from the sprayer and the average estimated amount of spray passing through the breathing zone were 0.1 and 0.006 ml spray/person, respectively. Using these data total systemic exposure can be estimated as follows: [UK PSD 2008b]"

4.3.217 Using these data total systemic exposure from spray drift at the time of application can be estimated as follows for field crop (boom) sprayers – turf application:

Systemic exposure = (PDE x SC x % absorbed + PIE x SC x 100%)/BW

Where:

PDE = potential dermal exposure (ml spray)

PIE = potential inhalation exposure (ml spray)

SC = concentration of active substance in spray (2.10 mg a.s./ml spray)

% absorbed = percentage dermal absorption (46%)

BW = bodyweight (60 kg)

$$\frac{(0.1 \times 2.10 \times 0.46) + (0.01 \times 2.10)}{60} = 0.002 \text{ mg/kg bw/day}$$

4.3.218 Assuming an application of 600 ml endosulfan 350 EC in 100 litres water (2.10 mg/ml), no protection from clothing and 100% inhalation, retention and absorption of PIE, the estimated bystander exposure is 0.002 mg/kg bw. This is equivalent to 10% of the AOEL of 0.0192 mg/kg bw/day.

Field crop (boom) sprayers: to simulate label uses

4.3.219 Using these data total systemic exposure from spray drift at the time of application can be estimated as follows for field crop (boom) sprayers – label uses:

Systemic exposure = (PDE x SC x % absorbed + PIE x SC x 100%)/BW

Where:

PDE = potential dermal exposure (ml spray)

PIE = potential inhalation exposure (ml spray)

SC = concentration of active substance in spray (0.7 mg a.s./ml spray)

% absorbed = percentage dermal absorption (46%)

BW = bodyweight (60 kg)

$$\frac{(0.1 \times 0.7 \times 0.46) + (0.01 \times 0.7)}{60} = 0.0007 \text{ mg/kg bw/day}$$

4.3.220 Assuming an application of 600 ml endosulfan 350 EC in 100 litres water (0.7 mg/ml), no protection from clothing and 100% inhalation, retention and absorption of PIE, the estimated bystander exposure is 0.0007 mg/kg bw. This is equivalent to 3.4% of the AOEL of 0.0192 mg/kg bw/day.

Exposure from inhalation of pesticide which volatilises from the crop or soil surface after the application has been made

4.3.221 The potential exists for longer term exposure to pesticide vapour which may occur after the plant protection product has been applied, for example residents who live adjacent to an area that has been treated with a plant protection product and who might be in this location for 24 hours per day. A large number of non-UK studies have been published which report the monitoring of outdoor air concentrations of pesticides after they have been applied to crops. From these studies the highest 24 hour time weighted average concentration in air for orchard sprayers (and a 21 hour time weighted average value for boom sprayer applications) have been determined. These values may be used generically [UK PSD 2008b].

Broadcast air assisted and knapsack sprayers – orchard application

4.3.222 Indicative exposures for adults and children to endosulfan vapour post-application following applications of endosulfan 350 EC made via broadcast air assisted sprayers is predicted using a surrogate value for residues in air adjacent to treated crops from Californian Environmental Protection Agency studies. Monitoring of chlorpyrifos residues in air over 72 hours adjacent to a 24 ha orange orchard provided a highest time weighted average estimate of 15 µg/m3/24h during application using air assisted sprayers. Time weighted average estimates for each of the 24 hour periods monitored were of 13, 15 and 4.9 µg/m3/24h. The meteorological conditions recorded during the chlorpyrifos study included wind speeds up to 20 km/h during application (the application was stopped on the first day of application due to rising wind speeds) and temperatures up to 42°C. These data are expected to represent a worse case for endosulfan as chlorpyrifos (vapour pressure 2.3 x 10-3 Pa at 25 °C) is a more volatile compound than endosulfan which has a lower vapour pressure (α endosulfan = 1.05 x 10^{-3} Pa ; β endosulfan = 1.38 x 10^{-4} Pa).

4.3.223 An adult weighing 60 kg and a 3-5 year old child weighing 15 kg,[21] breathing 15.2 and 8.3 m3/day,[22] respectively, of air containing 15

[21] Adults 60 kg is the 50th percentile for UK 16-24 yrs females, children 15 kg is the average values for UK 2 and 3 yrs males and females: 1995-7 Health Surveys for England.

µg/m3/24h would potentially be exposed to 0.0038 and 0.0083 mg/kg bw/day. Whilst the children's indicative exposure is below the AOEL (43% of 0.0192 mg/kg bw/day), in view of the differences in volatility between chlorpyrifos and endosulfan this exposure model is expected to over estimate air residues of endosulfan post-application. It is also noted that the 15 µg/m3/24h TWA value was the highest of the three concurrent 24 hour periods monitored and repeated exposure would not be expected at these air levels.

Field crop (boom) sprayers: to simulate turf application

"For applications made using field crop (boom) sprayers, exposure to vapour post application is predicted from studies conducted in Germany, where lindane (vapour pressure = 5.6 x 10-3 Pa at 25 C), parathion (1.3 x 10-3 Pa at 25 C) and pirimicarb (4 x 10-3 Pa at 25 C) were applied in field trials to provide measurements of residues in air adjacent to treated crops (Siebers et al 2000). Each active substance was applied at the same rate (g a.s./ha) and in the same water volume. Applications were achieved using field crop sprayers fitted with 12 metre booms. Monitoring of residues in air over 21 hours, 10 metres downwind of treated barley plots, provided 21 hour time weighted air concentrations of 0.29 and 0.58 µg/m3 (lindane), 0.07 and 0.12 µg/m3 (parathion) and <0.02 and 0.04µg/m3 (pirimicarb). The meteorological conditions during the trial included wind speeds of up to 23.4 km/h and temperatures up to 28°C. The study authors report wind speeds in the second trial (Trial B) were significantly higher (2 to 3X) than in the first trial (Trial A) and this is expected to have contributed to the variability of these results. It is noted that the higher 21 hour TWA value for each active substance was determined from Trial B." [quote from UK PSD 2008b]

4.3.224 In view of the small size of this data set (2 trials for each of the three active substances) a precautionary approach is to use a value of 1 µg/m3 to predict bystander exposure from vapour after application of the spray [UK PSD 2008b]. An adult weighing 60 kg and a 3-5 year old child weighing 15 kg, breathing 15.2 and 8.3 m3/day, respectively, of air containing this residue level, would potentially be exposed to 0.000253 and 0.0006 bw/day. The highest of these is 3% of the AOEL (0.0192 mg/kg bw/day for endosulfan).

[Note: endosulfan vapour pressure: α endosulfan = 1.05 x 10^{-3} Pa ; β endosulfan = 1.38 x 10^{-4} Pa]

Field crop (boom) sprayers: to simulate label uses

4.3.225 Noting the same limited data set is used:

An adult weighing 60 kg and a 3-5 year old child weighing 15 kg, breathing 15.2 and 8.3 m3/day, respectively, of air containing this residue level, would

[22] Long term inhalation rates (mean values) for adult males (19-65 + yrs) for children 3-5 yrs: US EPA Exposure Factors Hand Book.}[UK PSD 2008b].

potentially be exposed to 0.000253 and 0.0006 mg/kg bw/day. The highest of these is 3% of the AOEL (0.0192 mg/kg bw/day for endosulfan).

Exposure through contact with spray drift contaminated surfaces

> *"It is possible that spray drift fallout from applications may be deposited in private gardens adjacent to treated areas, and individuals in such locations may become exposed through contact with such deposits. A possible scenario that illustrates a significant opportunity for exposure would be children playing in a garden which has been subject to spray drift fallout. It is possible to estimate such exposures using spray drift fallout values used for aquatic risk assessment purposes (Rautmann et al, 2001) and the approach used by the United States Environmental Protection Agency to estimate residential exposure from contact with treated lawns (USA EPA 1998 / 1999 / 2001). The exposure assessment reported … considers the scenario of a small child playing on a lawn …*
>
> *For products which may be applied to crops on more than one occasion the theoretical worse case is to consider children's exposure from the maximum total dose which may be applied, i.e. to assume that there is no dissipation in foliar residues between successive treatments. This approach may be refined where data are available to refine the estimated residues." [quoted from UK PSD 2008b]*

4.3.226 The small child playing on a lawn leads to three potential exposures: dermal (skin contact); hand-to-mouth (sucking contacted fingers and thumbs); and, object-to-mouth (eating/sucking soil, grass etc.).

Broadcast air assisted and knapsack sprayers – orchard application

Children's dermal exposure

4.3.227 Systemic exposures via the dermal route were calculated using the above drift fallout values and the following equation for broadcast air assisted and knapsack sprayers – orchard application:

$$SE(d) = \frac{AR \times DF \times TTR \times TC \times H \times DA}{BW}$$

$$SE(d) = \frac{26 \times 0.10 \times 0.05 \times 5200 \times 2 \times 0.46}{15} = 41.5\ \mu g/kg\ bw$$

Where:

SE(d) = systemic exposure via the dermal route

AR = field application rate, 1.3 kg/ha x 2 applications = 26 $\mu g/cm^2$

DF = drift fallout value, i.e. assumed average of 10% from broadcast air assisted sprayer applications

TTR = turf transferable residues – the EPA default value of 5% was used in the estimate

TC = transfer coefficient – the standard EPA value of 5200 cm^2/h was used for the estimate

H = exposure duration for a typical day (hours) – this has been assumed to be 2 hours which matches the 75th percentile for toddlers playing on grass in the EPA Exposure Factors Handbook

DA = percent dermal absorption (46%)

BW = body weight - 15kg which is the average of UK 1995-7 Health Surveys for England values for males and females of 2 and 3 yrs

Children's hand-to-mouth exposure

4.3.228 Hand-to-mouth exposures were calculated using turf transferable residue levels using the following equation for broadcast air assisted and knapsack sprayers – orchard application:

$$SE(h) = \frac{AR \times DF \times TTR \times SE \times SA \times Freq \times H}{BW}$$

$$SE(h) = \frac{26 \times 0.10 \times 0.05 \times 0.50 \times 20 \times 20 \times 2}{15} = 3.47 \text{ µg/kg bw}$$

Where:

SE(h) = systemic exposure via the hand-to-mouth route

AR = field application rate, 1.3 kg/ha x 2 applications = 26 $\mu g/cm^2$

DF = drift fallout value, i.e. assumed average of 10% from broadcast air assisted sprayer applications

TTR = turf transferable residues – the EPA default value of 5% derived from transferability studies with wet hands was used in the estimate

SE = saliva extraction factor – the default value of 50% was used

SA = surface area of the hands – the assumption used here is that 20 cm^2 of skin area is contacted each time a child puts a hand in his or her mouth (this is equivalent to the palmar surface of three figures and is also related to the next parameter)

Freq = frequency of hand to mouth events/hour – for short term exposures the value of 20 events/hours is used, this is the 90th percentile of observations that ranges from 0 to 70 events/hour

H = exposure duration (hours) – this has been assumed to be 2 hours which matches the 75th percentile for toddlers playing on grass in the EPA Exposure Factors Handbook

BW = body weight - 15kg which is the average of UK 1995-7 Health Surveys for England values for males and females of 2 and 3 yrs

Children's object-to-mouth exposure

4.3.229 Object to mouth exposures were calculated using turf transferable residue levels using the following equation for broadcast air assisted and knapsack sprayers – orchard application:

$$SE(o) = \frac{AR \times DF \times TTR \times IgR}{BW}$$

$$SE(o) = \frac{26 \times 0.10 \times 0.20 \times 25}{15} = 0.87 \text{ µg/kg bw}$$

Where:

SE(o) = systemic exposure via mouthing activity

AR = field application rate, 1.3 kg/ha x 2 applications = 26 µg/cm^2

DF = drift fallout value, i.e. assumed average of 10% from broadcast air assisted sprayer applications

TTR = turf transferable residues the default value of 20% transferability from object to mouth assessments was used

IgR = ingestion rate for mouthing grass/day – this was assumed to be equivalent to 25cm^2 of grass/day

BW = body weight – 15kg which is the average of UK 1995–7 Health Surveys for England values for males and females of 2 and 3 yrs.

Children's total exposure from broadcast air assisted and knapsack sprayers – orchard application

4.3.230 Children's total exposure was estimated as the sum of the dermal, hand-to-mouth, and object to mouth exposures, which was 0.0458 mg/kg bw/day (45.84 µg/kg bw/d). This total exposure represents 239% of the AOEL (0.0192 mg/kg bw/day).

Field crop (boom) sprayers: to simulate turf application

Children's dermal exposure

4.3.231 Systemic exposures via the dermal route were calculated using the above drift fallout values and the following equation for field crop (boom) sprayers – turf application:

$$SE(d) = \frac{AR \times DF \times TTR \times TC \times H \times DA}{BW}$$

$$SE(d) = \frac{21 \times 0.01 \times 0.05 \times 5200 \times 2 \times 0.46}{15} = 3.35 \text{ µg/kg bw}$$

Where:

SE(d) = systemic exposure via the dermal route

AR = field application rate, 2.10 kg/ha x 1 applications = 21 μg/cm^2

DF = drift fallout value, i.e. assumed average of 1% from field crop (boom) sprayer applications

TTR = turf transferable residues – the EPA default value of 5% was used in the estimate

TC = transfer coefficient – the standard EPA value of 5200 cm^2/h was used for the estimate

H = exposure duration for a typical day (hours) – this has been assumed to be 2 hours which matches the 75th percentile for toddlers playing on grass in the EPA Exposure Factors Handbook

DA = percent dermal absorption (46%)

BW = body weight - 15kg which is the average of UK 1995-7 Health Surveys for England values for males and females of 2 and 3 yrs

Children's hand-to-mouth exposure

4.3.232 Hand-to-mouth exposures were calculated using turf transferable residue levels using the following equation for field crop (boom) sprayers – turf application:

$$SE(h) = \frac{AR \times DF \times TTR \times SE \times SA \times Freq \times H}{BW}$$

$$SE(h) = \frac{21 \times 0.01 \times 0.05 \times 0.50 \times 20 \times 20 \times 2}{15} = 0.28 \text{ μg/kg bw}$$

Where:

SE(h) = systemic exposure via the hand-to-mouth route

AR = field application rate, 2.10 kg/ha x 1 applications = 21 μg/cm^2

DF = drift fallout value, i.e. assumed average of 1% from field crop (boom) sprayer applications

TTR = turf transferable residues – the EPA default value of 5% derived from transferability studies with wet hands was used in the estimate

SE = saliva extraction factor – the default value of 50% was used

SA = surface area of the hands – the assumption used here is that 20 cm^2 of skin area is contacted each time a child puts a hand in his or her mouth (this is equivalent to the palmer surface of three figures and is also related to the next parameter)

Freq = frequency of hand to mouth events/hour – for short term exposures the value of 20 events/hours is used, this is the 90th percentile of observations that ranges from 0 to 70 events/hour

H = exposure duration (hours) – this has been assumed to be 2 hours which matches the 75th percentile for toddlers playing on grass in the EPA Exposure Factors Handbook

BW = body weight - 15kg which is the average of UK 1995-7 Health Surveys for England values for males and females of 2 and 3 yrs

Children's object-to-mouth exposure

4.3.233 Object to mouth exposures were calculated using turf transferable residue levels using the following equation for field crop (boom) sprayers – turf application:

$$SE(o) = \frac{AR \times DF \times TTR \times IgR}{BW}$$

$$SE(o) = \frac{21 \times 0.01 \times 0.20 \times 25}{15} = 0.07 \text{ µg/kg bw}$$

Where:

SE(o) = systemic exposure via mouthing activity

AR = field application rate, 2.10 kg/ha x 1 applications = 21 µg/cm^2

DF = drift fallout value, i.e. assumed average of 1% from field crop (boom) sprayer applications

TTR = turf transferable residues the default value of 20% transferability from object to mouth assessments was used

IgR = ingestion rate for mouthing grass/day – this was assumed to be equivalent to 25cm^2 of grass/day

BW = body weight - 15kg which is the average of UK 1995-7 Health Surveys for England values for males and females of 2 and 3 yrs.

Children's total exposure from field crop (boom) sprayers – turf application

4.3.234 Children's total exposure was estimated as the sum of the dermal, hand-to-mouth, and object to mouth exposures, which was 0.0037 mg/kg bw/day (3.7 µg/kg bw/d). This total exposure represents 19% of the AOEL (0.0192 mg/kg bw/day).

Field crop (boom) sprayers: to simulate label uses

Children's dermal exposure

4.3.235 Systemic exposures via the dermal route were calculated using the above drift fallout values and the following equation for field crop (boom) sprayers – label uses:

$$SE(d) = \frac{AR \times DF \times TTR \times TC \times H \times DA}{BW}$$

$$SE(d) = \frac{14 \times 0.01 \times 0.05 \times 5200 \times 2 \times 0.46}{15} = 2.23 \text{ µg/kg bw}$$

Where:

SE(d) = systemic exposure via the dermal route

AR = field application rate, 0.7 kg/ha x 2 applications = 14 µg/cm^2

DF = drift fallout value, i.e. assumed average of 1% from field crop (boom) sprayer applications

TTR = turf transferable residues – the EPA default value of 5% was used in the estimate

TC = transfer coefficient – the standard EPA value of 5200 cm^2/h was used for the estimate

H = exposure duration for a typical day (hours) – this has been assumed to be 2 hours which matches the 75th percentile for toddlers playing on grass in the EPA Exposure Factors Handbook

DA = percent dermal absorption (46%)

BW = body weight - 15kg which is the average of UK 1995-7 Health Surveys for England values for males and females of 2 and 3 yrs

Children's hand-to-mouth exposure

4.3.236 Hand-to-mouth exposures were calculated using turf transferable residue levels using the following equation for field crop (boom) sprayers – label uses:

$$SE(h) = \frac{AR \times DF \times TTR \times SE \times SA \times Freq \times H}{BW}$$

$$SE(h) = \frac{14 \times 0.01 \times 0.05 \times 0.50 \times 20 \times 20 \times 2}{15} = 0.19 \text{ µg/kg bw}$$

Where:

SE(h) = systemic exposure via the hand-to-mouth route

AR = field application rate, 0.7 kg/ha x 2 applications = 14 µg/cm^2

DF = drift fallout value, i.e. assumed average of 1% from field crop (boom) sprayer applications

TTR = turf transferable residues – the EPA default value of 5% derived from transferability studies with wet hands was used in the estimate

SE = saliva extraction factor – the default value of 50% was used

SA = surface area of the hands – the assumption used here is that 20 cm^2 of skin area is contacted each time a child puts a hand in his or her mouth (this is equivalent to the palmer surface of three figures and is also related to the next parameter)

Freq = frequency of hand to mouth events/hour – for short term exposures the value of 20 events/hours is used, this is the 90th percentile of observations that ranges from 0 to 70 events/hour

H = exposure duration (hours) – this has been assumed to be 2 hours which matches the 75th percentile for toddlers playing on grass in the EPA Exposure Factors Handbook

BW = body weight - 15kg which is the average of UK 1995-7 Health Surveys for England values for males and females of 2 and 3 yrs

Children's object-to-mouth exposure

4.3.237 Object to mouth exposures were calculated using turf transferable residue levels using the following equation for field crop (boom) sprayers – label uses:

$$SE(o) = \frac{AR \times DF \times TTR \times IgR}{BW}$$

$$SE(o) = \frac{14 \times 0.01 \times 0.20 \times 25}{15} = 0.05 \text{ µg/kg bw}$$

Where:

SE(o) = systemic exposure via mouthing activity

AR = field application rate, 0.7 kg/ha x 2 applications = 14 µg/cm^2

DF = drift fallout value, i.e. assumed average of 1% from field crop (boom) sprayer applications

TTR = turf transferable residues the default value of 20% transferability from object to mouth assessments was used

IgR = ingestion rate for mouthing grass/day – this was assumed to be equivalent to 25cm^2 of grass/day

BW = body weight - 15kg which is the average of UK 1995-7 Health Surveys for England values for males and females of 2 and 3 yrs.

Children's total exposure from field crop (boom) sprayers – label uses

4.3.238 Children's total exposure was estimated as the sum of the dermal, hand-to-mouth, and object to mouth exposures, which was 0.0025 mg/kg bw/day (2.47 µg/kg bw/d). This total exposure represents 13% of the AOEL (0.0192 mg/kg bw/day).

Summary of bystander and residential risk from spray drift

Table 34: Bystander exposure estimates

Scenario		Bystander Exposure Estimates Compared to AOEL [a]		
		Field crop (boom) sprayers		Broadcast Air Assisted
		Label uses [b]	Turf application [c]	Citrus [d]
Exposure from spray drift at the time of application		0.0007 [e] 3.4%	0.002 10%	0.037 192%
Exposure from inhalation of volatilised pesticide	Adult (60kg)	0.000253 1.3%	0.000253 1.3%	0.0038 20%
	Child (15kg)	0.0006 3%	0.0006 3%	0.0083 43%
Exposure through contact with spray drift contaminated surfaces	Children's dermal exposure [f]	2.23	3.35	41.5
	Children's hand-to-mouth exposure [f]	0.19	0.28	3.47
	Children's object-to-mouth exposure [f]	0.05	0.07	0.87
	Children's total exposure [e]	0.0025 13%	0.0037 19%	0.046 239%

[a] AOEL = 0.0192 mg/kg bw/day

[b] field application rate, 0.7 kg a.i./ha x 2 applications

[c] field application rate, 2.1 kg a.i./ha x 1 applications

[d] field application rate, 1.3 kg a.i./ha x 2 applications

[e] mg/kg bw/day

[f] µg/kg bw

Conclusions on bystander and residential exposure estimates from spray drift:

4.3.239 Table 34 above summarises bystander and residential exposure estimates. The estimated exposures from the UK PSD models for boom sprayers over field crops, to simulate label and turf use patterns, indicate that absorbed doses may reach up to 19% of the AOEL. This suggests little risk to bystanders during application, to residents from volatilised residues, or to children playing on contacted lawns.

4.3.240 However, the estimated exposures from the UK PSD models for broadcast air-assisted sprayers in orchards, to simulate citrus use patterns, indicate that absorbed doses may reach up to 192% of the AOEL for bystanders during application, and the risks to residents, particularly children from volatilised residues and residues deposited on lawns etc would be high (children: volatilised exposure, 43% of AOEL; plus, surface residues, 239%).

4.3.241 The Agency notes that the model assumptions are conservative, in that they assume that the spray from two applications is cumulative in the case of orchard air blast spraying and that the child is exposed to the dermal, hand to mouth and object to mouth exposures for a period of 2 hours, relatively

close (about 10 metres) from the orchard boundary which is a relatively unlikely scenario. The Agency also notes that the comparison is made with the AOEL, which is the health benchmark appropriate for regular daily exposure for about 3 months. Such a comparison is likely to overestimate the risk for the bystander exposed on an occasional basis.

Exposure from treated sports turf

4.3.242 The Agency is aware that one of the current uses of endosulfan in New Zealand is to suppress earthworms in sport turf, to prevent cast.

4.3.243 To try and assess any risks to users from this use of endosulfan, the UK PSD Bystander Exposure Guidance Document (2008b) model to estimate systemic exposures via the dermal route has been used. Several factors have been changed from those used to estimate children's exposures above:

$$SE(d) = \frac{AR \times DF \times TTR \times TC \times H \times DA}{BW}$$

$$SE(d) = \frac{21 \times 1.00 \times 0.05 \times 43000 \times 2 \times 0.46}{70} = 593.4\ \mu g/kg\ bw$$

Where:

SE(d) = systemic exposure via the dermal route

AR = field application rate, 2.10 kg/ha x 1 applications = 21 $\mu g/cm^2$

DF = drift fallout value, assumed average of 100% as no loss is anticipated from direct application (rather than from drift)

TTR = turf transferable residues – the EPA default value of 5% was used in the estimate

TC = transfer coefficient – the 20-minute Jazzercise activity EPA value of 43,000 cm^2/h was used for the estimate (see below)

H = exposure duration for a typical day (hours) – this has been assumed to be 2 hours which matches the 75th percentile for toddlers playing on grass in the EPA Exposure Factors Handbook [Assume same for sports people]

DA = percent dermal absorption (46%)

BW = body weight - 70kg default adult

Transfer Coefficient (TC):

The dermal transfer coefficient was set from Jazzercise studies of adults in contact with treated surfaces for 20 minutes, resulting in a normalised hourly dermal transfer coefficient of 43,000 cm^2/hr. The 20-minute Jazzercise activity represents a 1-hour activity for short-term exposure or a 2-hour activity for intermediate-term exposure. (CARES 1.0; March 20, 2002). The 20-minute Jazzercise TC appears to be the best available data to cover New Zealand field sports, such as soccer, touch, cricket and hockey when used in full for a 2 hour period. It is noted that this TC may significantly underestimate exposures from sports such as rugby or league when greater ground contact is made.

4.3.244 Sports person's total exposure was estimated as 0.59 mg/kg bw/day (593.4 µg/kg bw/d), which represents >1000% of the AOEL (0.0192 mg/kg bw/day).

4.3.245 The Agency has been advised that watering-in is recommended after applying endosulfan to sports turf, which could significantly reduce exposures:

"When used in turf for earthworm control, endosulfan is watered in immediately after application by a sprinkler irrigation system applying 12mm of irrigation without runoff. It is therefore washed off the turf surface, minimizing the risk of dislodgeable residues affecting turf users. In the soil its very high organic carbon partitioning coefficient adsorbs it to the soil organic matter (and clay particles). It is then held very tightly and doesn't move much." (Walmsley, B., in Sports Field Forum New Zealand Monthly Newsletter April 2008 Vol 3 (3)).

4.3.246 However, the Agency does not currently have the necessary information to further refine this risk estimate for sports turf.

Conclusions on the risks to sports people after the use of endosulfan on turf:

4.3.247 Although sports people's total exposure is estimated under the models to be >1000% of the AOEL, the Agency notes that watering-in could significantly reduce the estimated exposures. This, together with the reported current practice of no more than one annual treatment and an appropriate Restricted Entry Interval (REI) in the case of "ground contact" sports, may result in the risks being acceptable.

Conclusions on human health risk assessment

4.3.248 The toxicology profile of endosulfan has been well addressed internationally, and few significant data gaps remain.

4.3.249 Endosulfan has high acute oral and inhalation toxicity, but is less toxic via the dermal route due to relatively incomplete absorption. Neurotoxicity is the primary effect observed both acutely and chronically in both humans and animals.

4.3.250 Endosulfan has not been proven to be mutagenic, carcinogenic, or a reproductive or developmental toxicant.

4.3.251 The Agency has set an AOEL = 0.0192 mg/kg bw/day and, confirmed the ADE = 0.006 mg/kg bw/day.

4.3.252 No New Zealand exposure data for endosulfan are available for mixers, loaders, applicators, re-entry workers, bystanders or residents, so estimates of exposure have been modelled where possible. If further information on the effects of Restricted Entry Intervals (REIs) and PPE during re-entry

activities can be supplied to the Agency, the worker exposure estimates can be refined to New Zealand use patterns.

4.3.253 Risks to operators involved in mixing, loading and applying endosulfan for outdoor crops (including hand-held application) in accordance with current labelled application rates (0.7kg a.i./ha) are estimated as acceptable, provided that adequate (PPE) is used. The required PPE includes gloves during mixing and loading; gloves, visor, hood, overalls and boots during application.

4.3.254 Risks to operators involved in mixing and loading within glasshouses are acceptable provided adequate PPE is used. Risks to workers within glasshouses have not been separately modelled but are assumed to be unacceptable. For that reason, application should be by remote automated systems.

4.3.255 Risks to operators for turf and citrus applications even if full PPE (including respiratory protection) is used are high. This is due to the application rates being higher than for the current label uses for both turf and citrus and the different application method for citrus only.

4.3.256 Risks to workers re-entering areas treated in accordance with label uses, including glasshouse use, indicate that risks are acceptable provided appropriate PPE is used or REIs are applied.

4.3.257 Risks to bystanders and residents are estimated as acceptable for boom application to turf and in accordance with the label uses. However, risks to bystanders and residents from air-blast applications in citrus are estimated as unacceptably high at current application rates and procedures.

4.3.258 Risks to sports people from use of endosulfan on treated turf are acceptable if application is in accordance with the current standard practices involving watering in and one annual treatment and an appropriate REI is applied (in the case of "ground contact" sports such as rugby, football or hockey and for public parks where children may play).

Assessment of benefits (positive effects)

Assessment of benefits to the environment

Reduced adverse effects on non-target species (including honey bees)

4.3.259 Information provided by industry during the preparation of this application suggests that honeybees and ladybirds are less susceptible to endosulfan than some pest species due to more rapid metabolism to inactive metabolites (Kern,1990). This allows predators and parasites of important pests to play an economic role in pest control, where honey bees and bumble-bees play a vital part in agriculture/ horticulture through their activities as pollinators. In some countries, endosulfan is authorised for use during the flowering/blooming period. However, despite laboratory data that suggest that endosulfan is toxic, there is uncertainty as to whether such effects occur in the field (see assessment of environmental risks above).

Conclusions on environmental benefit assessment:

4.3.260 One potentially significant positive effect on the environment identified by industry while preparing this application was reduced adverse effects on non-target species, including honey bees. Evidence supporting this included information about countries where endosulfan is authorised for use during flowering periods. The assessment of risks to bees and non-target organisms noted that there was uncertainty regarding effects in the field and that the results were inconclusive. It is expected that there will be similar uncertainty about any positive effects, and therefore such effects are not able to be considered further. This remains an area of significant uncertainty.

Assessment of benefits to human health and safety

Reduced risks to people from ability to control earthworms and reduce castings which can cause injury through uneven surfaces

4.3.261 The inability to control earthworms and more importantly their castings can create or exacerbate potential safety issues on turfed areas. Essentially wormcasts make surfaces more uneven and more slippery. The most common safety issues relate to:

- Variable and unpredictable ball bounce particularly for summer sports such as cricket and softball;
- Variable and unpredictable footing for both winter and summer sports. For example, increased incidence of collapsed scrums;
- Loss of vehicular control by staff and user groups (golfers using carts or motor bikes) on undulating/hilly sites such as golf courses. Note: Most vehicles used on turf facilities are fitted with turf type tyres which lack the traction associated with agricultural equipment;
- Increased risks for jockeys and horses from poor traction on race tracks associated with muddy surfaces.

4.3.262 It is possible that people may be injured in this way, however no evidence is available to indicate the number and extent of injuries caused by earthworm activity on sports fields, race courses and golf courses (etc) and similarly no evidence to support an assessment of the degree to which endosulfan reduces health impacts.

Reduced risk to air travellers from reduction in risk of bird strike

4.3.263 Bird strike is a major concern for airports around the world, and the presence of worms in grassed areas is considered to be a hazard since it encourages birds. The primary concern of airport managers is to ensure the safety of travellers. During the preparation of this application, several New Zealand airports stressed to the Agency the importance of endosulfan to control earthworms and hence deter birds. It is not known to what degree airports rely on endosulfan and whether it is a preferred product or simply used because it is one of a range of possible products. It was indicated that

one benefit of endosulfan was the length of protection that it provided. However, no comparative analysis was provided.

Conclusions on human health and safety benefit assessment:

4.3.264 It appears that there are health and safety benefits to air passengers from the use of endosulfan, however the full extent of its use in New Zealand is not known. It is known that some airports use endosulfan to control earthworms and thus indirectly reduce the risk of birdstrike but the significance or relative importance of endosulfan is not known. Since earthworm control is a precaution, the direct effect is not able to be assessed.

Assessment of benefits to society and community

Reduced stress to farmers, horticulturalists and turf managers knowing that endosulfan is available as a backstop product

4.3.265 Endosulfan is used in a range of areas including agriculture, horticulture and turf management. The information available suggests that it has value in particular circumstances in all of these areas (see also beneficial effects on the market economy).

4.3.266 It is evident, as mentioned earlier, that while endosulfan may not be a first choice in agriculture and horticulture, it is seen as a backstop application. There is thus a social and community benefit accruing to users of reduced stress from knowing that if (or when) pest numbers get out of control endosulfan is available and will be effective.

Reduced concern on part of managers of sports facilities and sports participants

4.3.267 There is an indirect positive effect on society and community that accrues to managers of sports facilities and sports participants associated with knowing that these facilities can be kept in good condition such that injury is less likely to occur from worm activity.

Reduced risk of playing areas being closed/enhanced turf quality for sports

4.3.268 This indirect effect is linked to the previous positive effect.

Conclusions on society and community benefit assessment:

4.3.269 The first of these three effects is a direct effect, while the second two are indirect effects. While they are all valid positive effects or benefits of the availability of endosulfan, it is not clear how the second two might be assessed in terms of the marginal effect. The direct effect of reduced stress is probably the most important of the three. Additional information from submissions may provide evidence to support the size of this effect and the likelihood of it being realised.

Assessment of benefits to the market economy

Reduced cost of control of insects in the agricultural and horticultural sectors

4.3.270 Endosulfan belongs to the unique class of "dioxathiepin" chemicals. In New Zealand, it has been stated that it provides a much needed cost effective crop protection tool in a variety of situations, and that it is important in IPM and Resistance Management programmes. Because it is claimed to have low toxicity to honey bees in field situations, it may be a preferred insecticide for use on cross-pollinating crops.

4.3.271 Endosulfan has a wide spectrum of control and has immediate population knockdown capabilities. Some industry representatives state that it is "soft" on beneficial insects, which allows the farmer to use it in IPM. However robust information which shows a lack of effects on bees in the field has not been provided to the Agency.

4.3.272 Information received indicates that the 'last resort' aspect of the use of endosulfan is of particular importance to the citrus industry , however the size of the positive effect of the availability of endosulfan is not known in terms of the size of the industry and the proportion of the crop that would be threatened if endosulfan were not available. For example, it has been reported that endosulfan may be essential when insect populations are extreme. For example, the very high potato tuber moth pressure during the hot dry conditions this past (2007/8) summer would have put the crop at risk, if endosulfan had not been available.

Reduced cost of control of earthworms (range of possible costs) and less need to resurface areas

4.3.273 Information received from the turf industry during the preparation of this application, states that endosulfan provides the most cost effective and reliable means presently available for controlling earthworms.

4.3.274 Treatment with endosulfan allows expensive, modern drainage systems such as sand carpet fields to perform to expectation and for their full anticipated lifespan of approximately 15 years (construction cost: approx $180,000/field). In the event that earthworms are not controlled, the drainage rate of a sand carpet sports field and hence the performance of the field can be severely compromised within 1 – 2 years of construction.

Reduced maintenance costs

4.3.275 The industry also submits that if endosulfan were not available maintenance costs for a sand field would increase by approximately 125% p.a. Anecdotal evidence indicates that the maintenance costs for soil-based fields will also be significantly higher (50-100% p.a. – approx) than where earthworms are treated.

4.3.276 On sand-based fields, increased volumes of sand are required to counter the negative effects of earthworm casting. However, sand is becoming increasingly expensive and difficult to source.

4.3.277 This information is supported by relative costs of control of earthworms, indicating that the only other products on the market at present are more than twice the cost per hectare, and require considerably more frequent application.

Reduced cost of control of earthworms at airports

4.3.278 The health and safety aspect of control of earthworms at airports has been considered above. The costs aspect of this control is not known as no information is available about costs of alternative means of either removing earthworms or using other techniques for removing birds.

Reduced cost of development and testing of new products as pests do not develop resistance

4.3.279 As discussed in the identification section despite intensive use of endosulfan only a few cases of temporary insect resistance have been reported. Endosulfan has a unique mode of action with respect to all other currently used insecticides available on the New Zealand market.

4.3.280 The industry notes that due to new insecticidal chemistry being very selective in mode of action, resistance can develop very quickly. To prolong the useful life of such products there must be other products to use in rotation with them. User groups have indicated they believe endosulfan is valuable in this context and that the loss of endosulfan could increase the overuse of other products or combinations of them with the consequence of increasing resistance.

4.3.281 Industry has claimed that due to the development of resistance or restricted use of organophosphates, endosulfan will become even more important within the resistance strategies for the future. Synthetic Pyrethroid (SP) resistance is widespread in a number of insects and crops. It has been demonstrated that if the use of SPs is stopped for a period of time (length of time will be different for each insect population – but at least several years) this resistance in the insect population can diminish to a level where SPs become effective again. There must be a range of products with different modes of action for growers to choose from while SPs are unavailable and endosulfan is one such product.

4.3.282 While the value of endosulfan as a product that can be used in this way to combat resistance, there is no evidence to support a significant effect (benefit) on the market economy. It is further noted that whether endosulfan remains available or not is unlikely to have an impact on the development of new products since such decisions will be made based on a range of drivers of which the existence of this product will be only one.

Ability to be able to 'salvage' crops

4.3.283 Growers have indicated that endosulfan has value in that it can be used to 'salvage' crops when all other means of insect control have failed. While the use of endosulfan may mean that a crop is not able to be exported to the intended market because of residue testing, the crop may be able to be sold to a different market, possibly including a local market, that does not require such stringent testing. It would be very difficult to estimate any value for this positive effect and there may be an ethical concern about changing a market for these reasons.

Conclusions on market economy benefit assessment

Reduced cost of control of insects in the agricultural and horticultural sectors

4.3.284 Five potential positive effects (benefits) have been identified and discussed. These are:

- Reduced cost of control of insects in the agricultural and horticultural sectors;
- Reduced cost of control of earthworms and less need to resurface areas;
- Reduced cost of control of earthworms at airports;
- Reduced cost of development and testing of new products as pests do not develop resistance;
- Ability to be able to 'salvage' crops.

4.3.285 Endosulfan is a cheaper product than a number of other insecticides available, both from the perspective of the cost per application and also the number of applications required. However, without developing and costing a range of specific scenarios it is not possible to place a value on the size of the effect that accrues to the agriculture and horticulture sectors and to turf managers.

4.3.286 Reduced cost of development and testing of new products is a commercial decision that would be made by chemical companies and cannot easily be included in this assessment without further information. It should also be noted that it is a private cost.

4.3.287 The ability to be able to salvage crops is potentially important, but examples of how this has been applied would be needed for it to be assessed properly.

Summary of assessment of benefits

4.3.288 Some of the information suggests that endosulfan is an important element in IPM because it is less harmful to some non-target species including honey bees. Other information states that the lack of effects on bees in the field is unproven. This matter is therefore an area of significant uncertainty.

4.3.289 There are indirect health and safety benefits to air passengers from the use of endosulfan, but the extent of the benefit is unknown since this is only one element in reducing the risk of birdstrike.

4.3.290 Turf managers have indicated that there are social and economic benefits from the availability of endosulfan for control of earthworms. Endosulfan is cost effective and turf managers submit that it provides the best control. There are social and economic benefits to agriculturalists and horticulturalists as well from knowing that there is a 'last resort' insecticide available, and from the availability of a comparatively cheap and long lasting insecticide.

4.4 Relationship of Māori to the environment

4.4.1 The Agency used the framework contained in the ERMA New Zealand User Guide "Working with Māori under the HSNO Act 1996" to assess this application.

Adverse effects

4.4.2 The Agency notes that endosulfan triggers a number of hazardous properties giving rise to the potential for cultural risk including the deterioration of the mauri of taonga flora and fauna species, the environment and the general health and well-being of individuals and the community.

4.4.3 In addition, the use of this substance has the potential to inhibit the ability of iwi/Māori to fulfil their role as kaitiaki, particularly in relation to the guardianship of waterways given the highly ecotoxic nature of the substance to aquatic environments.

Mauri

4.4.4 The Agency notes that agrichemical trespass and or inappropriate persistence in the environment may result in adverse effects to the mauri of taonga and people. Biophysical effects associated with the use of the substance have been well described elsewhere in Section 4 and will not be repeated here other than to note that significant uncertainty exists relating to any flow on effects of an intangible cultural nature.

4.4.5 Mauri is the indivisible quality of the totality of an organism enabling it to move and live in accordance with the conditions and limits of its existence (Durie, 2003). It is the mauri that binds the physical and spiritual essence of things together. The mauri is therefore a form of energy, generating, regenerating, upholding creation and ensuring harmony and balance to the processes of the earths ecosystems. Māori assert that the use of toxic substances disrupts mauri and interferes with the basic structure of relationships between generations and between species. The potential long term effects of this disruption remain unknown. The Agency considers there currently to be insufficient evidence to provide an appropriate degree

of certainty that the use and management of endosulfan does not adversely effect mauri even with appropriate controls in place.

Kaitiakitanga

4.4.6 The role of Māori as kaitiaki has been formally recognised (including in the Resource Management Act 1991) as guardians and/or stewards of New Zealand's natural resources. Kaitiakitanga is the undertaking of duties and obligations inherited from the atua (gods) over the realms of those atua in accordance with Māori protocols and traditions (ERMA New Zealand 2004). Understanding traditional Māori knowledge relating to the dynamics of mauri and the relationships of the natural world, including being able to recognise and address issues, are key to the role of kaitiaki.

4.4.7 The occurrence of adverse effect to the mauri of taonga species or people, places increased pressure on kaitiaki in terms of their ability to continue to oversee the natural resources within their region. The Agency considers that the relative levels of uncertainty relating to adverse effects arising from the use and management of endosulfan may raise concern over the ability of kaitiaki to recognise and address issues as they arise.

Hauora

4.4.8 Effects on human health and wellbeing are described elsewhere in Section 4. The Agency considered whether Māori were disproportionately affected by the adverse effects arising. The absence of data made this difficult to assess though it is likely that any effect would be similar to those impacting on communities generally.

Assessment

4.4.9 Māori were not specifically consulted regarding this application. However the Agency has received clear messages at several hui with iwi/Māori resource managers that unless substances provide clear benefits to outweigh potential risk, they generally oppose the ongoing use of the substance. It is likely that, in the absence of further information regarding benefits, submissions from Māori would seek the revocation of the approvals for endosulfan.

4.4.10 Having regard to the information outlined here and elsewhere in this application, the Agency considers a moderate impact from the use of endosulphan on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna and other taonga assuming that existing controls are complied with.

Treaty of Waitangi

4.4.11 Section 8 of the Act requires the Authority, when considering applications, to take into account the principles of the Treaty of Waitangi. Of particular

relevance to this application is the principle of active protection affirmed by the Court of Appeal in the *Lands* case (1987).

4.4.12 It refers to the Crown's obligation to take positive steps to ensure that Māori interests are protected, and to consider them in line with the interests guaranteed to Māori in Article II of the Treaty. Specifically the Court noted that "*... the duty of the Crown is not merely passive but extends to active protection of Māori people in the use of their lands and waters to the fullest extent practicable*" (Cooke 1987).

4.4.13 Taking into account the principle of active protection requires this application to provide sufficient evidence to show that the use of endosulfan poses no risk of adverse effects to native/endemic species and/or other taonga species, ecosystems and traditional Māori values, practices, health and well-being. In considering the level of uncertainty described in relation to the adverse effects noted above, the Agency considers that this application may currently be viewed as being inconsistent with the principle of active protection.

Section Five – International Considerations

5.1.1 Endosulfan products have been removed from the market in a number of countries. The European Union (2005) withdrew authorisation for plant protection products containing endosulfan, except in four countries where a number of essential uses were authorised until 30 June 2007. The authorised uses were: Greece, cotton, tomato, peppers, pears, potato, alfalfa; Spain, hazel nut, cotton, tomato; Italy, hazel nut; Poland, hazel nut, strawberry, gerbera, ornamental bulbs. These reviews and subsequent action were based on the unacceptable risks to workers and the fate and behaviour of endosulfan in the environment, in particular its lack of degradation, persistence, potential for long range transport and potential to bioaccumulate.

5.1.2 The USEPA (2002), Australian APVMA (2005) and Canadian PMRA (2004) have all reassessed the use of endosulfan and restricted its use and put in place measures to mitigate worker and environmental risks.

5.1.3 A summary of the control measures taken as a part of these reviews (and a comparison against existing HSNO controls) is included in Appendix H.

5.1.4 Further overseas action concerning endosulfan includes the recommendation from the Rotterdam Convention Chemical Review Committee, 23 March 2007, that endosulfan be included in the Prior Informed Consent (PIC) procedure under the Rotterdam Convention. This recommendation was based on the grounds that endosulfan poses unacceptable risks to the environment. A draft decision to formalise the inclusion of endosulfan in the Convention has been prepared and its adoption will be considered at a Conference of the Parties in Rome in October 2008[23].

5.1.5 In July 2007, the European Commission submitted a proposal to the Stockholm Secretariat that endosulfan be considered as a candidate for inclusion under the Stockholm Convention on Persistent Organic Pollutants (POPs). The proposal concluded that endosulfan is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and environmental effects. The proposal was discussed at the third meeting of the Persistent Organic Pollutants Review Committee (POPRC-3: November 2000) which concluded that vital information required for its consideration of endosulfan was missing and deferred further consideration until the POPRC-4 meeting in November 2008.

5.1.6 The Agency notes these overseas reviews and other international initiatives and is of the view that they support this application for the reassessment of endosulfan.

[23] UNEP/FAO/RC/COP.4/9

Section Six – Likely Effects of the Substance Being Unavailable

6.1.1 Endosulfan is used as an insecticide registered for use on the crop/pest combinations shown in Table 6. 'Off label' uses include turf management and citrus.

6.1.2 With the exception of bronze beetle on berries, other products are registered for all of these crop/pest combinations (Appendix I). The Agency notes that a number of these products are themselves listed on the Chief Executive's Reassessment Priority List and that it does not currently have sufficient information to know whether these apparent alternative substances are practicable alternatives, or whether there are issues that would prevent their use, such as local resistance. It is expected that submissions will provide more information that can then be considered by the Authority in its evaluation of the application.

6.1.3 The Agency has been advised that endosulfan has a number of important advantages that are not recognised simply by listing the existence of alternatives. These are described in Section 4, but can be summarised as follows:

- Broad spectrum insecticidal/ acaricidal efficacy on difficult to control target pests.
- Useful for resistance management as it belongs to a different class of chemicals with a unique mode of action.
- Tool for IPM due to high selectivity on pollinators and many beneficial insects.
- Relatively non-toxic to beneficial insects.
- Excellent crop tolerance – no phytotoxicity.

6.1.4 Therefore if endosulfan was unavailable other problems could arise:

- Combinations and mixtures of other insecticides would be necessary to control the pests.
- Depending on the alternatives chosen a significant effect on non-target invertebrates could be expected, leading to pest infestation increases or to higher use of other insecticides.
- The risk of development of resistance to other insecticides is possible.
- Increased cost to users/industry.

6.1.5 Alternative products for the treatment of turf are also available. Baker et al (1998) list carbaryl, carbendazim and gamma-HCH+ thiophanate-methyl, although there is some doubt as to the effectiveness of some of these products.[24] In this respect, the Agency also notes that carbaryl and

[24] http://www.oxfordcroquet.com/care/worms/index.asp

carbendazim (with benomyl) are substances on the Chief Executive's Reassessment Priority List. Carbendazim is very ecotoxic in the aquatic and soil environment and is also persistent. It is not approved for use in the United States, and uses in other countries such as Canada are restricted. Carbaryl has the potential to cause adverse effects to the nervous system in humans at low concentrations. It is also suspected of being carcinogenic and is very ecotoxic to fish and honeybees. The United States, United Kingdom, Canada and Australia have reviewed, and imposed more stringent measures to mitigate the risks posed by carbaryl products.

6.1.6 The New Zealand Sports Turf Institute has also advised[25] that the following non-chemical (physical) means have been used overseas where endosulfan is not available:

- acidification of the soil profile to reduce earthworm populations. However, this has implications for the availability of plant nutrients and the survival of some grass types;
- greater reliance on heavier sand topdressing to discourage earthworm feeding activity and dilute castings. However, use of sand in the way in New Zealand would impose substantial costs on sports users.

[25] NZSTI report dated June 2008.

Section Seven – Overall Evaluation and Recommendations

7.1 Overall evaluation

7.1.3 Under section 29 of the Act, the Authority may approve this application if, after taking into account:

- any controls which may be imposed on the substance; and
- all effects of the substance during its lifecycle; and
- the likely effects of the substance being unavailable,

the positive effects of the substance outweigh the adverse effects. Conversely, if the adverse effects outweigh the positive effects, the Authority may decline the application (and thus prohibit the use of endosulfan).

7.1.4 In the absence of exposure information, the Agency has used quantitative exposure assessment models to determine the levels of risk to human health and the environment. This exposure modelling has produced indicative levels of risk that, in many cases, are high.

7.1.5 On the basis of this information, the Agency's interim evaluation is that there are significant (non-negligible) risks associated with the use of endosulfan in New Zealand which potentially outweigh the benefits.

7.1.6 This evaluation takes into account that the Agency does not currently have sufficient reliable information in order properly to assess or verify:

- the benefits of using the substance; and/or
- the likely effects of the substance being unavailable.

7.1.7 Although some information on these matters has been provided to the Agency in the course of preparing this application, the statutory public submissions period allows a further opportunity for information to be provided which could result in the Authority establishing a higher level of benefits.

7.1.8 In addition, there is the following uncertainty in the assessment of the adverse effects:

- There is a lack of New Zealand-relevant environmental exposure data, including geographic locations of use in relation to aquatic environments. Higher tier modelling performed overseas is not directly applicable to New Zealand conditions and use patterns. To date, no such modelling has yet been performed to reflect New Zealand conditions and use patterns.

- There is also a lack of New Zealand-relevant human exposure data. In the absence of such data, exposure modelling has been used to determine the human health risks associated with the use of endosulfan products, and it is noted that the modelling includes conservative assumptions, so that the risks may be overestimated.

7.1.9 Clauses 29 and 30 of the Methodology[26] provides that where there is scientific and technical uncertainty, the Authority must consider the materiality of the uncertainty and if it cannot be resolved to its satisfaction, the Authority must take into account the need for caution in managing the adverse effects of the substance.

7.1.10 Given the information currently before it, and taking account of the need for caution, the Agency proposes the preliminary recommendations set out below.

7.2 Preliminary recommendations

The following recommendations are preliminary only. An important part of the reassessment process is public submissions on the application. These public submissions are likely to have an effect on the final outcome of the reassessment.

On the basis of its evaluation of whether the risks associated with the use of endosulfan in New Zealand outweigh the benefits, ERMA New Zealand proposes the following preliminary recommendations to ensure that practices are safe for people and the environment:

1. That the use of endosulfan be prohibited for:
   - aerial and domestic use of the substance on the basis that these are not uses to which it is currently put (and the relevant risks have not been assessed as part of this application); and
   - airblast application for citrus on the basis that risks to operators and bystanders are currently assessed as very high.

2. That use on turf be restricted to one annual treatment, followed immediately by watering in, with no use of the treated area in the case of "ground contact" sports use and public parks where children may play, for a period of at least 48 hours following treatment (noting, however, that the operator exposures are high even with full PPE, so the feasibility of a lower application rate needs to be explored).

3. That the following Restricted Entry Intervals (REIs) be imposed for other uses, where PPE is not used when re-entering:
   - 48 hours for all crops not listed below;
   - 3 days for sweetpotato, mustard, radish, turnip;
   - 4 days for brassicas (broccoli, cabbage, cauliflower, brussels sprouts);

[26] Hazardous Substances and New Organisms (Methodology) Order 1998 (SR 1998/217).

- 6 days for blueberries;
- 10 days for sweetcorn.

In respect of the issue of REIs, ERMA New Zealand notes that:

- although re-entry restrictions can be specified on New Zealand labels under HSNO regulations, the clearer, more prescriptive approach recommended above is in line with requirements introduced by overseas' agencies;
- consideration will need to be given to an appropriate REI for greenhouse use;
- consideration will need to be given to longer REIs in the case of 'pick your own' berry orchards to take account of the exposure of pickers; and
- REIs may not be necessary in respect of post-application turf maintenance activities (for example, mowing/rolling) unless the work involves direct exposure.

4. That a no-spray buffer zone around waterbodies and the edges of treated crops be introduced due to high level of risks to the aquatic environment and to soil fauna (ERMA New Zealand currently considers a 100 m buffer zone may be appropriate on the basis of overseas' analyses of the effectiveness of buffer zones).

5. That reduced (maximum) application rates (kg a.i./ha per application/season) and/or limits on the number of applications (for example, per season) be introduced for some uses in order to lower the risks to the environment and people (noting the measures of this type proposed by some overseas agencies).

6. That suitable PPE be stipulated for different types of application and at different stages of the lifecycle (mixing/loading; application).

Finally, if the Authority's overall evaluation favours retention of some or all of the endosulfan approvals, ERMA New Zealand **recommends** the following classification changes:

- for all formulations, replace 6.1C overall acute toxicity classification with 6.1A based on inhalation toxicity;
- replace the current 6.3B classification on Substance D with a 6.3A classification;
- remove the 6.8B classification applied to Thionex Insecticide Solvesso formulation;
- replace the current 9.2C classification on endosulfan and all its formulations with a 9.2A classification;
- assign an approval number to the Thionex Insecticide Solvesso formulation;
- change the packing group assigned to endosulfan and all formulations containing endosulfan from PG I to PG II.

Section Eight – Summary of Public Information

8.1 Names of the substances for the public register

- Endosulfan CAS 115-29-7 (HSR002846)
- Emulsifiable concentrate containing 350 g/litre endosulfan (Substance A) (HSR000679)
- Emulsifiable concentrate containing 350 g/litre endosulfan (Substance B) (HSR000678)
- Emulsifiable concentrate containing 350 g/litre endosulfan (Substance C) (HSR000487)
- Emulsifiable concentrate containing 350 g/litre endosulfan (Substance D) (HSR000677)

8.2 Purpose of the application for the public register

8.2.1 An application for the reassessment of endosulfan and formulations containing endosulfan under section 63 of the Act. This arises from a decision by the Environmental Risk Management Authority that there are grounds for reassessment of this substance, under section 62(3) of the Act (RES07003).

8.3 Use categories of the substances

Main Category	4	Wide dispersive use
Industry Categories	1	Agricultural industry
Function/Use Category	38	Pesticides

Signed_____

Chief Executive, ERMA New Zealand

Dated _____ 2008

References

Agency of Toxic Substances and Disease Registry (ATSDR). 2000. Toxicological Profile for Endosulfan. http://www.atsdr.cdc.gov/toxprofiles/tp41.html

Aleem A, Malik A. 2005. Genotoxicity of the Yamuna River water at Okhla (Delhi), India. *Ecotox Environ Saf*. 61(3):404–12.

Amaraneni SR. 2006. Distribution of pesticides, PAHs and heavy metals in prawn ponds near Kolleru lake wetland, India. *Environ Int* 32(3):294–302.

ANZECC. 2000. *Water Quality Guidelines*. http://www.mincos.gov.au/__data/assets/pdf_file/0020/316136/gfmwq-guidelines-vol2-8-3b.pdf

APVMA. 1998. The NRA review of endosulfan, Section 7, Environmental Assessment.

APVMA. 1998a. The NRA review of endosulfan, Section 3, Chemistry Assessment.

APVMA. 2005. The reconsideration of approval of the active constituent endosulfan, registrations of products containing endosulfan and their associated labels. *Final review report and regulatory decision, Review Series 2*.

Arnot JA, Gobas FAPC. 2004. A food web bioaccumulation model for organic chemicals in aquatic ecosystems. *Environ Toxicol Chem* 23(10):2343–2355.

Arrebola FJ, Martinez Vidal JL, Fernandez-Gutierrez A. 2001. Analysis of endosulfan and its metabolites in human serum using gas chromatography-tandem mass spectrometry. *J Chromatogr Sci* 39(5):177–82.

Baedelt, H, Idstein, Dr. H, Krebs, B. 1992. Endosulfan – emulsifiable concentrate – (352 g/1) Investigation of the degradation behavior in soil under field conditions (Stufe 2 in accordance with the BBA Guideline, Part IV, 4–1) 30 June 1992 Study Document.

Bajpayee M, Pandey AK, Zaidi S, Musarrat J, Parmar D, Mathur N, Serth PK, Dhawan A. 2006. DNA damage and mutagenicity induced by endosulfan and its metabolites. *Environ Mol Mutagen* 47(9):682–92.

Baker, S.W., Binns, D.J., Kirby, E.C. 1998. Reduction in rates of earthworm casting on turf areas using carbendazim, carbaryl, and gamma-HCH + thiophanate-methyl *Journal of Turfgrass Science* Vol. 74 (1998).

Barakat AO, Kim M, Qian Y, Wade TL. 2002. Organochlorine pesticides and PCB residues in sediments of Alexandria Harbour, Egypt. *Mar Poll Bull* 44(12):1421–1434.

Barlas N, Cok I, Akbulut N. 2006. The contamination levels of organochlorine pesticides in water and sediment samples in Uluabat Lake, Turkey. *Environ Monit Assess* 118:383–91.

Bastos CS, de Almeida RP, Suinaga FA. 2006. Selectivity of pesticides used on cotton (*Gossypium hirsutum*) to *Trichogramma pretiosum* reared on two laboratory-reared hosts. *Pest Manag Sci* 62:91–8.

Bhattacharya B, Sarkar SK, Mukherjee N. 2003. Organochlorine pesticide residues in sediments of a tropical mangrove estuary, India: implications for monitoring. *Environ Int* 29(5):587–592.

Biobest. 2008. Side effects manual – endosulfan. http://207.5.17.151/biobest/en/neven/default_result.asp

Bollmohr S, Day JA, Schulz R. 2007. Temporal variability in particle-associated pesticide exposure in a temporarily open estuary, Western Cape, South Africa. *Chemosphere* 68:479–88.

Botella B, Crespo J, Rivas A, Cerrillo I, Olea-Serrano MF, Olea N. 2004. Exposure of women to organochlorine pesticides in Southern Spain. *Environ Res* 96(1): 24–40.

Bouvier G, Blanchard O, Momas I, Seta N. 2006. Pesticide exposure of non-occupationally exposed subjects compared to some occupational exposure: a French pilot study. *Sci Total Environ* 366(1): 74–91.

Brasse D. 1985. Effects of endosulfan-containing insecticides on beneficial organisms and honey bees. *Nachrichtenbl Deut Pflanzenschutzd* 37: 54–58

Brun GL, MacDonald RM, Verge J, Aube J. 2007. Long-term atmospheric deposition of current-use and banned pesticides in Atlantic Canada; 1980–2000. *Chemosphere Sept [Epub ahead of print]*.

Burke ER, Holden AJ, Shaw IC. 2003. A method to determine residue levels of persistent organochlorine pesticides in human milk from Indonesian women. *Chemosphere* 50(4): 529–535.

Campoy, C, Olea-Serrano, F. Jime´nez, M. Baye´s, R. Can˜abate, F. Rosales, M.J. Blanca, E. Olea. N. 2001a. Diet and organochlorine contaminants in women of reproductive age under 40 years old. *Early Human Development 65 Suppl.* (2001) S173–S182.

California EPA. 2007. Endosulfan Risk Characterisation Report.

California DPR. 2008. Endosulfan Risk Characterisation Document Volume 1 Medical Toxicology and Worker Health and Safety Branches Department of Pesticide Regulation California Environmental Protection Agency.

Campoy C, Jimenz M, Olea-Serrano MF, Moreno-Frias M, Canabate F, Olea N, Bayes R, Molina-Font JA. 2001b. Analysis of organochlorine pesticides in human milk: preliminary results. *Early Hum Devel* 65(s2): S183–190.

Carlson DL, Basu I, Hites RA. 2004. Annual variations of pesticide concentrations in Great Lakes precipitation. *Environ Sci Technol* 38(20): 5290–6.

Carreno J, Rivas A, Granada A, Lopez-Espinosa MJ, Mariscal M, Olea N, Olea-Serrano F. 2007. Exposure of young men to organochlorine pesticides in Southern Spain. *Environ Res* 103: 55–61.

Carrera G, Fernandez P, Grimalt JO. 2002. Atmospheric deposition of organochlorine compounds to remote high mountain lakes of Europe. *Environ Sci Technol* 36: 2581–8.

Cerejeira MJ, Viana P, Pereira T, Silva E, Valerio MJ, Silva A, Ferreira M, Silva-Fernandes AM. 2003. Pesticides in Portuguese surface and ground waters. *Water Res* 37(5): 1055–1063.

Cerrillo I, Granada A, Lopez-Espinosa MJ, Olmos B, Jimenez M, Cano A, Olea N, Fatima Olea-Serrano M. 2005. Endosulfan and its metabolites in fertile women, placenta, cord blood, and human milk. *Environ Res* 98(2): 233–239.

Cerrillo I, Olea-Serrano MF, Ibarluzea J, Exposito J, Torne P, Laguna J, Pedraza V, Olea N. 2006. Environmental and lifestyle factors for organochlorine exposure among women living in Southern Spain. *Chemosphere* 62(11): 1917–1924.

Cooper SP, Burau K, Sweeney A, Robison T, Smith MA, Symanski E, Colt JS, Laseter J, Zahm SH. 2001. Prenatal exposure to pesticides: a feasibility study among migrant and seasonal farmworkers. *Am J Ind Med* 40(5): 578–85.

Damgaard IN, Skakkebaek NE, Toppari J, Virtanen HE, Shen H, Schramm KW, Petersen JH, Jensen TK, Main KM; Nordic Cryptorchidism Study Group. 2006. Persistent pesticides in human breast milk and cryptorchidism. *Environ Health Perspect.* 114(7): 1133113–8.

Davies, D.J. (26 March 2002) Endosulfan 350g/l EC Formulation: *In Vitro* Absorption of Endosulfan Through Human, Pig and Rat Epidermis CTL/JV1673/Regulatory/Report, Central Toxicology Laboratory, Alderley Park, Macclesfield.

Davis BNK and Williams, CT. 1990. Buffer zone widths for honeybees from ground and aerial spraying of insecticides. *Environmental Pollution* 63: 247–259.

Deger AB, Gremm TJ, Frimmel FH, Mendez L. 2003. Optimization and application of SPME for the gas chromatographic determination of endosulfan and its major metabolites in the ngL-1 range in aqueous solutions. *Anal Bioanal Chem* 376: 61–68.

Dubois M, Pfohl-Leszkowicz A, De Waziers I, Kremers P. 1996. Selective induction of the CYP3A family by endosulfan and DNA-adduct formation in different hepatic and hepatoma cells. *Environ Toxicol Pharmacol* 1(1): 249–256.

El Bakouri H, Ouassini A, Morillo Aguado J, Usero García J. 2007. Endosulfan sulfate mobility in soil columns and pesticide pollution of groundwater in Northwest Morocco. *Water Environ Res* 79(13): 2578–84.

ERMA. 2008. User Guide to the Thresholds and Classifications under the Hazardous Substances and New Organisms Act 1996.
http://www.ermanz.govt.nz/hs/tandc/index.html

EU. 2006. Notification of final regulatory action for endosulfan by the European Community ECB and UNEP/FAO/RC/CRC.3/10

Fletcher JS, Nellenssen JE and Pfleeger TG. 1994. Literature review and evaluation of the EPA food-chain (Kenaga) nomogram, an instrument for estimating pesticide residues on plants. *Environmental Toxicology and Chemistry* 13: 1383–1391.

Fukata H, Omori M, Osada H, Todaka E, Mori C. 2005. Necessity to measure PCBs and organochlorine pesticide concentrations in human umbilical cords for fetal exposure assessment. *Environ Health Perspect* 113:297–303.
http://www.ehponline.org/members/2004/7330/7330.html

GFEA-U. 2007. Endosulfan. Draft Dossier prepared in support of a proposal of endosulfan to be considered as a candidate for inclusion in the CLRTAP protocol on persistent organic pollutants. *German Federal Environment Agency – Umweltbundesamt Berlin, February.*

Gilmore, R, Sheets, L, Hoss, H. 2006. A Developmental Neurotoxicity Study with Technical Grade Endosulfan in Wistar Rats. Project Number: 201563, 05/D72/YF. Dated September 26, 2006. Corp. 1062 p. MRID# 46968301

Glin Lj, Kuiseau J, Thiam A, Vodouhe DS, Dinham B, Ferrigno S. 2006. *Living with Poison: Problems of Endosulfan in West Africa Cotton Growing Systems*. *Pesticide Action Network UK, London.* http://www.panna.org/files/livingWithPoison.pdf

Guerin TF, Kennedy IR. 1992. Distribution and dissipation of endosulfan and related cyclodienes in sterile aqueous systems: Implications for studies on biodegradation *J. Agric. Food Chem* 40: 2315–2323 (In CalEPA, 2007).

Harner T, Pozo K, Gouin T, Macdonald A-M, Hung H, Cainey J, Peters A. 2006. Global pilot study for persistent organic pollutants (POPs) using PUF disk passive air samplers. *Environ Poll* 144:445–52.

Health Canada. 2007. Preliminary Risk and Value Assessments of Endosulfan *Health Canada Rev2*.

Heather B, Robertson H. 1996. The Field Guide to the Birds of New Zealand.

Heimbach, F. 1985. Comparison of Laboratory Methods, Using Eisenia foetida and Lumbricus terrestris, for the Assessment of the Hazard of Chemicals to Earthworms. *J.Plant Dis.Prot*. (Z.Pflanzenkr.Pflanzensch.) 92(2):186–193.

Hernandez F, Pitarch E, Serrano R, Gaspar JV, Olea N. 2002. Multiresidue determination of endosulfan and metabolic derivatives in human adipose tissue using automated liquid chromatographic cleanup and gas chromatographic analysis. *J Anal Toxicol* 26(2): 94–103.

IOBC. 2005. Working document on selectivity of pesticides http://www.iobc.ch/2005/IOBC_Pesticide%20Database_Toolbox.pdf

JMPR. 1998. Endosulfan Joint FAO/ WHO Meetings on Pesticide Residues (JMPR).

Joy VC, Chakravorty PP. 1991. Impact of insecticide on nontarget microarthropod fauna in agricultural soil. *Ecotoxicol Environ Saf* 22(1): 8–16).

Kelly BC, Ikonomou MG, Blair JD, Morin AE, Gobas FAPC. 2007. Food web-specific biomagnification of persistent organic pollutants. *Science* 317: 236–9.

Kern, M. 1990. Insecticidal mode of action of Thiodan® (endosulfan). Hoechst report A46470 (translation of A43412).

Kennedy IR, Sanchez-Bayo F, Kimber SW, Hugo L, Ahmad N. 2001. Off-site movement of endosulfan from irrigated cotton in New South Wales. *J Environ Qual* 30:683–96. http://jeq.scijournals.org/cgi/reprint/30/3/683

Knight J, Holdsworth D, Mather, D. 2007. Country of origin and choice of food imports. *Journal of International Business Studies* 38: 107–125.

Lewis RJ. 1996. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1–3. New York, NY: Van Nostrand Reinhold, 1996. 1463 *SDB (Hazardous Substances Database)*.

Lino CM, da Silveira IN. 2006. Evaluation of organochlorine pesticides in serum from students in Coimbra, Portugal: 1997–2001. *Environ Res* 102: 339–51.

Lopez-Espinosa MJ, Lopez-Navarrete E, Rivas A, Fernandez MF, Nogueras M, Campoy C, Olea-Serrano F, Lardelli P, Olea N. 2007. Organochlorine pesticide exposure in children living in Southern Spain. *Environ Res Oct 1*; [Epub ahead of print].

Mackay, N, Arnold, D. 2005. Evaluation and interpretation of Environmental data on endosulfan in arctic regions. Cambridge Environmental Assessments-ADAS 14th October 2005 Report Number CEA.1 07.

Martinez Vidal JL, Moreno Frias M, Garrido Frenich A, Olea-Serrano F, Olea N. 2002. Determination of endocrine-disrupting pesticides and polychlorinated biphenyls in human serum by GC-ECD and GC-MS-MS and evaluation of contributions to the uncertainty of the results. *Anal Bioanal Chem* 372(7-8): 766–75.

Mast MA, Foreman WT, Skaates SV. 2007. Current-use pesticides and organochlorine compounds in precipitation and lake sediment from two high-elevation national parks in the western United States. *Arch Environ Contam Toxicol* 52: 294–305.

Menone ML, Aizpun de Moreno JE, Moreno VJ, Lanfranchi AL, Metcalfe TL, Metcalfe CD. 2000. PCBs and organochlorines in tissues of silverside (Odontesthes bonariensis) from a coastal lagoon in Argentina. *Arch Environ Contam Toxicol* 38: 202–8.

MfE. 2001. Valuing New Zealand's "Clean Green Image".

Miranda-Filho KC, Metcalfe TL, Metcalfe CD, Robaldo RB, Muelbert MMC, Colares EP, Martinez PE, Bianchini A. 2007. Residues of persistent organochlorine contaminants in southern elephant seals (Mirounga leonina) from Elephant Island, Antarctica. *Environ Sci Technol* 41: 3829–35.

Muir DC, Teixeira C, Wania F. 2004. Empirical and modelling evidence of regional atmospheric transport of current-use pesticides. *Environ Toxicol Chem* 23(10): 2421–2432.

Nath A, Sharma DC, Sharma ID. 1985. Metabolism of endosulfan in the Indian honey bee. *Experientia* 41: 1411–1412.

OECD, 2004 OECD Guideline for the testing of chemicals, Skin absorption *in vitro* method, No 428, (Adopted 13 April 2004).

Palmer-Jones T. 1959. Effect on honey bees of Thiodan applied to broad beans in a cage. *NZ J. of Agric. Res*. 2: 229–233.

Palmer-Jones T, Forster IW and Jeffery GL. 1959. Effect on honey bees of DDT and Thiodan applied from the air as sprays to Chou moellier. *NZ J. of Agric. Res*. 2: 481–487.

PANUPS. 1996. Endosulfan responsible for Alabama fish kill. *Pesticide Action Network North America.* http://www.panna.org

Ramanarayanan T., Allen R. 1999b. Endosulfan (AE F002671): Selection of Tier II Surface Water Exposure Assessment Scenarios Using a Geographical Information System and Natural Resources Databases. Unpublished study prepared by AgrEvo USA Company. 61 p. MRID # 44953101.

Ramanarayanan, T., Allen, R. 1999a. Endosulfan (AE F002671): Tier II Exposure Assessment; Sensitivity Analysis for PRZM (Ver 3.12), EXAMS (Ver 2.97.5) and AgDrift (Ver 1.02): Lab Project Number: 513BJ: B002224: BJ99E513. Unpublished study prepared by AgrEvo USA Company. 54 p. MRID 44953102.

Ramanarayanan, T.; Fischer, R.; Allen, R. 1999. Endosulfan (AE F002671): Tier II Surface Water Exposure Assessment and Comparison to Aquatic Toxicity End-Points: Lab Project Number: BJ99E514: B002255: WEI622.06-B. Unpublished study prepared by AgrEvo USA Company. 282 p. MRID 44953103.

Roberts et al (2007). 2007. Maternal Residence Near Agricultural Pesticide Applications and Autism Spectrum Disorders among Children in the California Central Valley Environmental Health Perspectives VOLUME 115 NUMBER 10 October 2007 1482–1489.

Saiyed H, Dewan A, Bhatnagar V, Shenoy U, Shenoy R, Rajmohan H, Patel K, Kashyap R, Kulkarni P, Rajan B, Lakkad B. 2003. Effect of endosulfan on male

reproductive development. Environ Health Perspect 111(16): 1958–62. http://www.ehponline.org/members/2003/6271/6271.pdf

Sanghi R, Pillai MK, Jayalekshmi TR, Nair A. 2003. Organochlorine and organophosphorus pesticide residues in breast milk from Bhopal, Madhya Pradesh, India. Hum Exp Toxicol 22(2): 73–6.

Schafer RB, Mueller R, Brack W, Wenzel K-D, Streck G, Ruck W, Liess M. 2007. Determination of 10 particle-associated multiclass polar and semi-polar pesticides from small streams using accelerated solvent extraction. Chemosphere Online 27 September.

Shen H, Main KM, Andersson A-M, Damgaard IN, Virtanen HE, Skakkebaek NE, Toppari J, Schramm K-W. 2008. Concentrations of persistent organochlorine compounds in human milk and placenta are higher in Denmark than in Finland. Hum Reprod 23(1): 201–210.

Shen H, Main KM, Virtanen HE, Damgaard IN, Haavisto A-M, Kaleva M, Boisen KA, Schmidt IM, Chellakooty M, Skakkebaek NE, Toppari J, Schramm K-W. 2007. From mother to child: investigation of prenatal and postnatal exposure to persistent bioaccumulating toxicants using breast milk and placenta biomonitoring. *Chemosphere* 67: S256–62.

Shen L, Wania F, Lei YD, Teixeira C, Muir DC, Bidleman TF. 2005. Atmospheric distribution and long-range transport behavior of organochlorine pesticides in North America. *Environ Sci Technol* 39(2):409–420.

Simonich SL, Hites RA. 1997. Relationships between socioeconomic indicators and concentrations of organochlorine pesticides in tree bark. *Environ Sci Technol* 31(4):999–1003. http://emt.oregonstate.edu/simonich/publications/EST%201997%20paper.pdf

Simonich SL, Hites RA. 1995. Global distribution of persistent organochlorine compounds. *Science* 269(5232): 1851–4. http://emt.oregonstate.edu/simonich/publications/Organochiorine%20Compounds.pdf

Sun P, Backus S, Blanchard P, Hites RA. 2006. Temporal and spatial trends of organochlorine pesticides in Great Lakes precipitation. *Environ Sci Technol* 40: 2135–2141.

Torres MJ, Folgoso CC, Reche FC, Velasco AR, Garcia IC, Arcas MM, Olea-Serrano F. 2006. Organochlorine pesticides in serum and adipose tissue of pregnant women in Southern Spain giving birth by caesarean section. *Sci Total Environ* 372(1): 32–38.

UK PSD, (2008a) Guidance for Post-Application (Re-entry Worker) Exposure Assessment, http://www.pesticides.gov.uk/approvals.asp?id=2422&link=%2 Fuploadedfiles%2FWeb%5FAssets%2FPSD%2FRe%2Dentry%2520worker%2520guid ance%5Ffinal%2520version%2Epdf

UK PSD, (2008b), Bystander Exposure Guidance Document

http://www.pesticides.gov.uk/approvals.asp?id=2428&link=%2Fuploadedfiles%2FWeb%5 FAssets%2FPSD%2FBystander%2520exposure%2520guidance%5Ffinal%2520version%2Epdf

Urban and Cook. 1986. *Hazard Evaluation Division Standard Evaluation Procedure: Ecological Risk Assessment*. *EPA 540/9-85-001.* United States Environmental Protection Agency Office of Pesticide Programs, Washington DC, USA.

US EPA. 2007c. Addendum to the Ecological Risk Assessment for Endosulfan. Memorandum to Special Review and Reregistration Branch. October 31. EPA-HQ-OPP-2002-0262-0063. http://www.regulations.gov

US EPA. 2002. Reregistration Eligibility Decision for Endosulfan. EPA 738-R-02-013. *Pollution, Pesticides and Toxic Substances (7508C),* United States Environmental Protection Agency. http://www.epa.gov/oppsrrd1/REDs/endosulfan_red.pdf

Usenko S, Landers DH, Appleby PG, Simonisch SL. 2007. Current and historical deposition of PBDEs, pesticides, PCBs, and PAHs to Rocky Mountain National Park. *Enviro Sci Technol* 41(21): 7235–41.

Vig K, Singh DK, Agarwal HC, Dhawan AK, Dureja P. 2008. Soil microorganisms in cotton fields sequentially treated with insecticides. *Ecotoxicol Environ Saf* 69(2): 263–76.

WHO (IPCS): International Chemical Safety Cards: 0742 Endosulfan (Mixed Isomers).

Yadav AS, Vashishat RK, Kakar SN. 1982. Testing of endosulfan and fenitrothion for genotoxicity in Saccharomyces cerevisiae. *Mutat Res* 105(6): 403–7.

Younglai EV, Foster WG, Hughes EG, Trim K, Jarrell JF. 2002. Levels of environmental contaminants in human follicular fluid, serum, and seminal plasma of couples undergoing in vitro fertilization. *Arch Environ Contam Toxicol* 43(1): 121–126.

Appendices

Appendix A – Human health hazard profile

Introduction

The information on the human health hazards of endosulfan available to the Agency for this reassessment, whether or not submitted, has been screened for relevance to the HSNO Act; scientific, particularly regulatory scientific rigour; and, whether or not the information with a positive or negative outcome adds significantly to the existing knowledge base.

The Act and Regulations made under it set out the parameters for each of the classifications of potential human health hazards. The Act also indicates a hierarchy of test protocols within each Classification to help, where necessary to determine where the weight-of-evidence lies. The Act defines relevance for the reassessment.

HSNO human health classifications are based on adverse effects. So, for a substance to receive a HSNO classification a relevant adverse effect must be shown in a scientifically sound manner.

Unfortunately, much of the information made available to the Agency for this application, did not meet these screening requirements, particularly that of relevancy to the Act.

Pharmacokinetics

The majority of endosulfan, regardless of exposure route, is excreted rapidly in faeces, with virtually no retention in tissues, despite the lipophilicity of endosulfan and its primary metabolite, endosulfan sulfate. Enterohepatic circulation, conjugation and elimination in the urine, is not a major route for endosulfan metabolism. At 120 hours, 88% of α-[^{14}C]endosulfan and 87% of β-[^{14}C] endosulfan had been eliminated. The default policy for DPR is that if oral absorption is 80% or greater, the absorption is assumed to be 100%. After endosulfan was dermally administered to rats, within 5 days 47.3% of the dose was absorbed and 95% of the absorbed material was eliminated. Fatty tissues had the highest endosulfan concentrations after dermal treatment. After oral treatment in rats, liver and kidney were the sites of greatest endosulfan concentration. These organs are likely the primary sites of biotransformation, since their weights increase after treatment, as do the concentrations and activities of xenobiotic metabolising enzymes such as P450s and glutathione-transferases [Cal DPR, 2008].

6.1 classification – Acute toxicity

Endosulfan is highly acutely toxic via the oral and inhalation routes in rats. It was also highly toxic via the dermal route in rabbits, but generally less toxic in other test species. Female rats were much more sensitive to the acute oral and dermal effects of endosulfan than males.

The key acute toxicity end points for endosulfan are given in Table 3.

The acute toxicity classifications for the formulations of endosulfan have been derived using the HSNO mixture rules based on the concentration of endosulfan present.

Acute oral toxicity

Using the endosulfan LD_{50} (oral) rat 22.7 mg/kg bw (Table 3) and a concentration of 350g/L, the mixture calculation gives LD_{50} (mix) = (100/35) * 22.7 = 64.9 mg/kg bw. This value is in the range 50 – 300 mg/kg bw, so the mixtures classify as 6.1C based on the endosulfan content.

Acute dermal toxicity

Using the endosulfan LD_{50} (dermal) 34 mg/kg bw (Table 3) the mixture calculation for dermal gives LD_{50} (mixture) = 100/35 * 34 = 97 mg/kg bw. Since the 6.1B (dermal) range is 50 – 200 mg/kg bw, the mixtures classify as 6.1B based on the endosulfan content.

Acute inhalation toxicity

Using the LC_{50} for endosulfan 13 mg/m^3 = 0.013 mg/L (Table 3), the mixture calculation gives LC_{50} (mixture) = (100/350) * 0.013 = 0.037 mg/L. Since the vapour pressure of the triggering component endosulfan is relatively low (vapour pressure of α endosulfan = 1.05 x 10^{-3} Pa, and β endosulfan = 1.38 x 10^{-4} Pa, Table 2) it is appropriate to assess the mixture LC_{50} against the range for dust/mist. The range for 6.1A (as dust/mist) is <0.05 mg/L so the mixtures trigger classification as 6.1A based on the endosulfan content.

6.3, 6.4 & 6.5 classification – Irritancy/sensitisation

Endosulfan was moderately irritating to the eyes but was not a dermal irritant in rabbits, nor was it a skin sensitiser in Guinea pigs.

No data were identified relating to the respiratory sensitisation potential of endosulfan, the deficiency of data in that area is noted.

Endosulfan Formulations

The skin irritation classifications of the formulated products are driven by the combination of components to give rise to the classifications in Table 4.

The eye irritation/corrosivity classifications of the formulated products are driven by a combination of endosulfan (an eye irritant) and other components to give rise to the classifications in Table 4.

Skin sensitisation (6.5B) is triggered in Substance A by a mixture component other than endosulfan.

6.6 classification – Mutagenicity/genotoxicity

For genotoxicity, numerous studies have been performed in bacteria, yeast, mammalian cells in culture and *in vivo* in laboratory animals. The overall assessment of genotoxic potential of endosulfan shows that tests are either positive or negative: bacterial systems (14/18 negative), micronucleus (2/2 negative), dominant lethal mouse (1/2 negative; positive only at 9.8 mg/kg b w/day and higher); *in vitro* cellular systems (mouse, rat, human; 3/7 negative; 2/7 equivocal) and in vivo (2/8 negative). There is some evidence for genotoxicity with endosulfan, especially in tests for chromosomal effects. However, in order to identify a positive effect *in vivo*, animals were treated at doses that exceed the maximally tolerated dose (MTD). Mortality would occur at the MTD thereby preventing tumour development through early death [Cal DPR, 2008].

Some studies were reported to be positive in the published literature (Chaudhuri et al., 1999; McGregor et al., 1988; Yadav et al., 1982; L'vova, 1984; Velazquez et al., 1984; Sobti et al., 1983; Sharma and Gautam, 1991; Martins, 2003, Daniel et al., 1986; Dubois et al., 1996 in Cal DPR, 2008), however, none was acceptable by FIFRA Guidelines (Tables 15 and 16). USEPA does not consider oral exposure (*in vivo* tests) of rats to be genotoxic; stating that "the data are inconclusive" (USEPA, 2000b in Cal DPR, 2008). USEPA also states that induction of chromosomal aberrations and gene mutations in *Drosophila melanogaster* (Velazquez et al., 1984 in Cal DPR, 2008) and in mice (Usha Rana and Reddy, 1986 in Cal DPR, 2008) complicate data analysis because some of the formulations of endosulfan may have contained epichlorohydrin, a known genotoxin, as a stabiliser (see Tables 14 and 15; USEPA, 2000b; Hoechst, 1990 in Cal DPR, 2008).

Table 14. Genotoxicity of Endosulfan (Gene Mutation Assays)

System/Strain	Concentration/Dose	S9[a]	Results	Ref[b]
Schizosaccharomyces pombe				
Haploid (4 hour exposure)	62.5, 125, 250, 500 ug/ml	+ / -	Negative	1
Salmonella typhimurium Strains				
TA98, TA100, TA1978, TA1535	Spot test	+ / -	Negative	2
TA1535, TA1537, TA1538, TA98, TA100	5, 10, 50, 100, 500, 1000, 5000 ug/plate	+ / -	Negative	3
TA1535, TA1537, TA1538, TA98, TA100	5, 10, 50, 100, 500, 1000, 5000 ug/plate	-	Negative	4
TA1538, TA98, TA1538	Not stated	-	Negative	5
TA1535, TA1536, TA1537, TA1538	Spot test	-	Negative	6
TA100, TA98, TA97a	41, 3256 mg/L	+ / -	Negative	7
TA100	Not stated	+ / -	Negative	8
TA1535/pSK 1002	30, 50, 100, 150, 500 ug/ml	-	Positive	9
TA98, TA97a, TA102, TA104, TA100	1, 5, 10, 20 ug/plate	+/-	Positive	10
Escherichia coli Strains				
WP2 hcr	5, 10, 50, 100, 500 ug/plate	-	Negative	4
Strain Not stated	Not stated	-	Negative	11
K12 (prophage λ) in WP2s (λ)	200, 400, 500 ug/ml	-	Positive	9
K12: AB1157, AB1886, AB2494, AB2463	10, 20, 30, 40, 50 mg/ml	-	Negative	9
K12 AB1157	10, 20, 30 mg/ml	-	Negative	9
Mouse Lymphoma				
L5178Y TK+/-	6.25, 12.5, 18.8, 25, 37.5, 50, 75, 100 ug/ml	+ / -	Negative	12
L5178Y TK+/-	3, 6, 12.5, 25, 50, 9, 14, 18.6, 23, 28 ug/ml	-	Positive	13
Bacillus subtilis				
H17, M45	20, 100, 200, 500, 1000, 2000 ug/disk	-	Negative	3
Saccharomyces cervisiae				
Strain not stated	**100, 500, 1000, 5000 ug/ml**	+ / -	**Negative**	**14***
D7	10, 100 ug/ml	-	Positive	15
T1/PG-154, T2/PG-155	10, 100 ug/ml	-	Positive	16

a - Supernatant fraction at 9,000 x g from homogenized rat livers (contains enzymes for metabolic activation).
b - References: 1.Mellano, 1984; 2. Dorough et al., 1978; 3. Shirasu et al., 1978; 4. Moriya et al., 1983; 5. Quito et al., 1981; 6. Adams, 1978; 7. Pednekar et al., 1987; 8. Shirasu, 1982; 9. Chaudhuri et al., 1999; 10. Bajpayee et al., 2006; 11. Fahrig, 1974; 12. Cifone, 1984a; 13. McGregor et al., 1988; 14. Milone & Hirsch, 1986; 15. Yadav et al., 1982; 16. L'vova, 1984 .
c - NA = Not applicable for some *in vivo* and/or *in vitro* tests.

[Cal DPR, 2008]

Table 15. Genotoxicity of Endosulfan (Chromosome Aberration and DNA Damage Assays)

System/Strain	Concentration/Dose	S9	Results[a]	Ref[b]
Micronucleus				
NMRI Mice	0.02, 1.0, 5.0 mg/kg	NA[c]	Negative	1
Swiss Albino	43.3 mg/kg	NA[c]	Negative	2
Dominant Lethal				
Albino Mice	5, 10 mg/kg (i.p.)	NA[c]	Negative	3
In vivo Swiss Albino Mice	9.8, 12.7, 16.6, 21.6 mg/kg	NA[c]	Positive	4
Human Lymphocytes				
***In vitro* cytogenics**	**1, 10, 100, 200 ug/ml**	+/-	**Negative**	**5***
In vitro	5, 100 ug/ml	-	Negative	6
In vitro LAZ-007	0.37, 3.71, 37.1 mg/kg	+	Positive	5
Mouse DNA Damage				
Bone Marrow (in vivo treatment)	0.2, 1.0, 5.0 mg/kg	NA[c]	Positive	7
Bone Marrow (in vivo treatment)	1.75, 3.5, 5.25 mg/kg	NA[c]	Positive	8
Bone Marrow (in vivo treatment)	1.0, 10 mg/kg	NA[c]	Positive	9
Chinese Hamster Ovary Cells (CHO)				
CHO *in vitro*	Not Stated	Unk	Negative	10
CHO *in vitro*	Not Stated	Unk	Negative	8
CHO *in vitro*: DNA damage, Comet Assay Human Lymphocytes: DNA damage, Comet	0.01, 0.05, 0.25, 1.0, 10 uM	NA	Positive	11
***In vivo* Rat or Mouse (vehicle = peanut oil)**				
Albino Mouse Spermatocytes	22, 32, 42 mg/kg	NA[c]	Positive	12
Rat Bone Marrow/Spermatogonia	11, 22, 36, 55 mg/kg, gavage 30d	NA[c]	Negative	13
Rat Spermatocytes	11, 22, 36.6, 55 mg/kg, gavage 5d	NA[c]	Negative	14
Rat Bone Marrow/Spermatocytes	11, gavage 5d	NA[c]	Negative	15
***In Vivo* Syrian Hamster**				
In vivo intraperitoneal treatment	8, 16, 40, 80 mg/kg	NA[c]	Positive	16
Unscheduled DNA Synthesis in Primary Rat Hepatocytes				
***In vitro* treatment**	**0.1, 0.25, 0.5, 1, 5, 10, 26, 51 ug/ml**	**NA[c]**	**Negative**	**17***
Human RBC *In vitro*				
In vitro treatment	0.001, 0.01, 0.1, 1.0 ug/ml	NA[c]	Positive	18
Drosophila Melanogaster *In vivo*				
Sex-Chromosome Loss after 24 hr	0, 50, 100, 200 ppm	NA[c]	Positive	19
Fetal Hepatocytes *In vitro*				
Human Blastoma, Quail & Rat Cells	50 uM	NA[c]	Pos & Neg[d]	20
Sister Chromatid Exchange (SCE), Micronuclei Test (MN), DNA Strand Breaks (SB): α- & β-isomers tested separately				
HepG2 Cells: Human Hepatocyte Cell Line	10^{-12} to 10^{-3} M; DMSO vehicle	-	α- SCE, MN: -- ; SB: + β- SCE, MN, SB: +	21

a - Supernatant fraction at 9,000 x g from homogenized rat livers (contains enzymes for metabolic activation).

b - References: 1. Cifone, 1983; 2. Usha Rani et al., 1980; 3. Arnold, 1972; 4. Milone & Hirsch, 1986; 5. Sobti et al., 1983; 6. Shirasu et al., 1978; 7. Kurinnyi et al., 1982; 8. Sharma & Gautam, 1991; 9. L'vova, 1984; 10. NTP, 1988; 11. Bajpayee et al., 2006; 12. Usha Rani & Reddy, 1986; 13. Dikshith et al., 1978; 14. Dikshith & Datta, 1977; 15. Dikshith and Datta, 1978; 16. Dzwonkowska & Hubner, 1986; 17. Cifone, 1984b; 18. Daniel et al., 1986; 19. Velazquez et al., 1984; 20. Dubois et al., 1996; 21. Lu et al., 2000.

c - NA = Not applicable for some *in vivo* and/or *in vitro* tests.

"* " and **Bold** depicts studies reviewed as acceptable under current FIFRA Guidelines.

[Cal DPR, 2008]

6.7 classification – carcinogenicity

Hepatocyte gap junctional intercellular communication was inhibited by endosulfan, as well as by the sulfate, lactone and ether metabolite. Gap junctional intercellular communication was also inhibited by both α- and β - isomers in primary Sprague-Dawley rat hepatocytes, as well as WB-F344 rat liver cell lines. While gap junctional intercellular communication might be considered to be a tumor promotional event, all studies reporting this effect were performed *in vitro*. In studies performed *in vivo* there has been no evidence to indicate that endosulfan is a tumor promotor [Cal DPR, 2008].

For evaluation of chronic toxicity and oncogenicity of endosulfan, there were 3 rat, 2 mouse and 1 dog dietary study, in addition to 1 dog study performed with endosulfan in capsules. One rat combined (chronic and oncogenicity), 1 mouse oncogenicity and 1 chronic dog study (all dietary) were acceptable based on FIFRA Guidelines. The primary effects in the rat studies were to the vascular system, and the kidney, along with a decrease in body weight gain. The mouse oncogenicity study showed mortality as the primary effect. In the mouse studies, a target organ was not identified. The primary effects observed in the chronic, dog-dietary study were mortality (premature termination) and neurotoxicity. The lowest NOEL for chronic studies was 0.57 mg/kg b w/day obtained in the chronic dog study (M: 0.57 mg/kg b w/day; F: 0.65 mg/kg b w/day) based on increased mortality, and neurotoxicity. Results for oncogenicity studies performed in the rat and the mouse showed no tumor incidence that was treatment-related, dose-related or otherwise different in incidence across dose groups. Endosulfan is categorised as "A4" (not classifiable as a human carcinogen) by the American Conference of Governmental Industrial Hygienists (Substances and Physical Agents and Biological Exposure Indices, Cincinnati, OH, 2005 in Cal DPR, 2008). USEPA states: "Cancer Determination: The carcinogenicity issue has been considered by the Health Effects Division--Cancer Peer Review Committee. The Committee agreed that 'there was no evidence of carcinogenicity' for endosulfan" Endosulfan is placed in Group E: Evidence of non-carcinogenicity for humans (Revision of Occupational and Residential Exposure/Risk Assessment for the Endosulfan Reregistration Eligibility Decision Document (RED); Revised; Docket number: EPA - HQ- OPP- 2005 – 0459; USEPA, 2007 in Cal DPR, 2008). The Canadian Preliminary Risk and Values Assessment for Endosulfan states "Endosulfan was not carcinogenic in mice or rats and was not genotoxic," (PMRA, 2007 in Cal DPR, 2008).

Endosulfan is not listed by the International Agency for Research on Cancer (IARC) as a carcinogen. Reports by Health Canada Pest Management Regulatory Agency (2007), European Union (2007), United States Environmental Protection Agency (2002) and the Agency for Toxic Substances and Disease Registry (2000) have all concluded that endosulfan is not carcinogenic.

6.8 classification – Reproductive/developmental toxicity

There were no reproductive effects related to treatment observed in studies that were well-designed with peer-reviewed protocols, studies with reproducible data and/or historical controls. Some studies in the open literature examined the effects of endosulfan on neonatal reproductive tract development, as well as effects on mature male reproductive tract. Most effects observed, however, were systemic, rather than reproductive. Effects in the acceptable FIFRA Guideline reproduction study were systemic (liver and kidney) and there were no effects in the reproductive parameters for

either sex. Many of the studies performed in the open literature had major deficiencies but supported the lack of reproductive effects in neonates, pups or adults of either sex [Cal DPR, 2008].

In addition to studies using regulatory protocols, the potential reproductive toxicity of endosulfan has been tested in various areas, and contributed to Cal DPR's conclusions:

- Neonatal/Prepubertal Reproductive Organs and Sex Hormones
- Gavage in Females During Pregnancy and Lactation, Sexual Development in Males
- Gavage in Adult Male Rats, Assessment of Reproductive Tract
- Endocrine Effects on Human Reproductive Systems (Epidemiological Studies)
- *In vitro* Effects on Steroidogenesis and Spermatogenesis
- *In Vivo* Effects on Steroidogenesis and Spermatogenesis
- Estrogenicity in *In Vivo/In Vitro* Assays
- Physiological Compensation in Mammalian Females

For example:

> *"An epidemiological study was performed to assess potential effects of aerial spraying of endosulfan on sexual maturation in children (Saiyed, et al., 2003). Endosulfan was the only pesticide that had been used (sprayed 2 - 3 times/year for 20 years) on cashew nut plantations located on hilltops in villages in northern Kerala, India. The village school children were exposed to endosulfan via air, water (runoff from irrigation) and soil. Control children (comparable status) were from a village 20 km away without any history of aerial endosulfan spraying. Male children (study n = 117; controls n = 90) aged 10 -19 years were to receive an examination for sexual maturity rating (SMR, pubic hair, testes and penis), a blood test to assess testosterone (T), luteinizing hormone (LH), follicle-stimulating hormone (FSH) and endosulfan residues (α-, β- and sulfate). Non participation in the SMR was 57% for the study and 33% for controls; however, in the 43% (n = 50) and 76% (n = 68), respectively, that did participate there was a statistically significant decrease in SMR for pubic hair, testicular and penis development with regard to R^2, intercept (b0), age (b1) and aerial exposure to endosulfan (AEE b3: Score = b0 + b1age) b2AEE). The study males with tested blood samples (n = 67) had lower than expected testosterone levels, considering age and LH in blood, compared to the control males (n = 46). In fact, the main study males had higher than expected LH levels, when compared to controls. Endosulfan residues α-, β- and sulfate individually, as well as total endosulfan, were all statistically significantly increased in the study males (n = 70), compared to controls (n = 45). The authors concluded that a follow-up should be performed on the children to understand the implications of the findings, in addition to performing a study with a larger sample size to validate the study findings. The study was acknowledged by the authors to be preliminary. Supplemental." [quote from Cal DPR, 2008].*

Developmental toxicity

In acceptable FIFRA Guideline developmental studies, the rabbit had no fetal effects, only maternal neurotoxicity and death at greater than 0.7 mg/kg/day. Rats, however, had decreased fetal weights and percent of live fetuses at greater than 2.0 mg/kg/day. Maternal toxicity occurred at doses lower than or equal to doses showing fetal effects. In addition to the developmental studies summarised below, a dietary developmental neurotoxicity study in rat was reviewed (Gilmore et al., 2006, Sheets, and Hoss, 2006 in Cal DPR, 2008).

6.9 classification – Target organ toxicity

Oral

The effects observed in laboratory animals from chronic dietary exposure to endosulfan are summarised in Table 13. Effects observed in the rat were different from those observed in the dog. In the rat, the chronic dietary NOEL was 0.6 mg/kg/day for males and 0.7 mg/kg/day for females based on decreased body weight gain, kidney enlargement, progressive glomerulonephrosis and glomerulonephritis, proteinuria, aneurysms (Ruckman et al., 1989 in Cal DPR, 2008). This study was acceptable according to FIFRA Guidelines [Cal DPR, 2008].

Table 13. The Chronic Effects of Oral Endosulfan Treatment and the NOELs and LOELs

Species	Exposure	Effect	NOEL mg/kg/d	LOEL mg/kg/d	Ref[a]
Rat M/F	104 week (diet)	Aneurysms and progressive glomerulonephrosis & nephritis; enlarged kidneys, proteinuria; decreased body weight gain	0.6 M 0.7 F	2.9 M 3.9 F	1*
Dog M/F	**1 year (diet)**	**Premature termination, clinical signs of neurotoxicity, decreased body weight gain and food consumption**	**0.57 M 0.65 F**	**2.09 M 1.98 F**	2*

a - 1. Ruckman et al., 1989; 2. Brunk, 1989
* - Designates studies that are acceptable, according to FIFRA Guidelines.
Bold = Definitive test for the critical NOEL for dietary effects.

[Cal DPR, 2008]

In dogs, neurotoxicity was the most sensitive endpoint for chronic oral endosulfan toxicity. The chronic study in dogs was performed with endosulfan administered in diet. In the dog, the chronic dietary NOEL was 0.57 mg/kg/day for males and 0.65 mg/kg/day for females, based on clinical signs of violent contractions of the upper abdomen and convulsive movements, extreme sensitivity to noise, frightened reactions to optical stimuli and jerky or tonic contractions in facial muscles, chaps and extremities and impairment of the reflex excitability and postural reactions (Brunk, 1989 in Cal DPR, 2008). It was necessary to sacrifice some of the dogs prematurely due to the clinical signs of neurotoxicity. In addition, body weights and food consumption were decreased. This study was acceptable according to FIFRA Guidelines [Cal DPR, 2008].

The dog appears to be very slightly more sensitive than the rat with regard to chronic effects. However, the dog study, with a critical NOEL of 0.57 mg/kg/day was similar to the NOEL obtained in the chronic dietary rat study (0.6 mg/kg/day). The two studies were performed by different methods, despite the fact that they are both considered oral, dietary studies. The dog study, with endosulfan administered in diet, was selected as the

definitive study. However, mortality and neurotoxicity occurred in dogs at 2.0 mg/kg/day, where this dose was tolerated in rats. At 2.9 mg/kg/day in male rats and at 3.8 mg/kg/day in female rats (highest doses tested), kidney enlargement and glomerulonephritis in females and aneurysms in males were increased. Rat mortality, however, at these high doses was comparable to the controls. Rats received the endosulfan treatment in their diet, and this may account for the apparent interspecies sensitivity differential. The chronic dog study was selected as the definitive study with a critical NOEL of 0.57 mg/kg/day since it appeared to be the more sensitive species when tested in an acceptable FIFRA Guideline study. The chronic rat study NOEL, virtually the same at 0.6 mg/kg/day, served to support the value obtained in the dog study. The chronic dietary NOEL of 0.57 will be used to determine MOE for both dietary and worker exposure (Table 13) [Cal DPR, 2008].

Dermal

There were no FIFRA Guideline, nor were their open literature studies that were acceptable for chronic dermal exposure to endosulfan technical. Therefore, the procedure is to use the chronic oral NOEL in dog (0.57 mg/kg/day) for determinations of MOEs for chronic dermal occupational exposures and for exposures to swimmers in surface water [Cal DPR, 2008].

Inhalation

An acceptable chronic inhalation exposure study was not available from the open literature or studies submitted by registrants to obtain a chronic inhalation NOEL. Therefore, an acceptable subchronic rat inhalation study with a NOEL of 0.0010 mg/L (0.194 mg/kg/day) was used to calculate the potential for chronic inhalation exposure to workers, and for exposure to endosulfan for bystander air (Hollander et al., 1984 in Cal DPR, 2008). In this study, endosulfan was administered by aerosol (nose-only) for 21 days at 6 hours per day, followed by a 29-day recovery. The NOEL for inhalation was based on emaciation, pale skin, squatting position and high-legged position, decreased bodyweight gain and food consumption, increased water consumption, and clinical chemistry parameters (reversed during recovery) [Cal DPR, 2008].

Neurotoxicity

The primary target of endosulfan is the central nervous system, as was observed in numerous studies, primarily in the rat. Endosulfan is a strong neurotoxin in animals (rabbits, rats, dog, mice, cow, cat, pig and lamb) as well as humans (see Illness Reports in Beauvais, 2008; Volume II in Cal DPR, 2008) as well as studies throughout the Toxicology Profile) but it does not induce delayed neurotoxicity in hens [Cal DPR, 2008].

> *"The acute gavage neurotoxicity study in rat showed a systemic NOEL of 12.5 mg/kg for males and 1.5 mg/kg for females, based on an increase in clinical signs (mortality, tonoclonic convulsions, coarse tremor, uncoordinated gait, increased salivation, stupor, prone position, increased fright reaction, squatting posture, stilted gait, irregular respiration, straddled hind limbs, decreased spontaneous activity, panting, bristled coat, flanks drawn in and narrowed palpebral fissure) in males at 25 mg/kg and*

greater and in females at 3 mg/kg and greater, lasting for 1 day. This difference between the sexes was also observed in the subchronic dietary neurotoxicity study in rats where the systemic NOELs were 37.2 mg/kg/day (HDT) for males and 16.6 mg/kg/day for females. The neurotoxicity parameters showed no treatment-related effects on FOB or motor activity in either sex at any dose. Other studies showed endosulfan interacts directly in the central nervous system to affect monoaminergic systems in different parts of the brain. This, in turn, affects memory and the learning operant paradigm. Endosulfan decreased sleeping time induced by chlorpromazine and was also shown in 3 studies to induce kindling, a model of secondary generalized epilepsy from repeated, low intensity electrical stimulation of limbic foci in the brain. Endosulfan also was shown to inhibit a noncompetitive blocker site for the GABAA receptor in rat. Most of the open literature studies reported below were performed at toxic doses to examine specific effects in the nervous system, primarily brain, therefore NOELs and LOELs were not achieved. Endosulfan is a chlorine channel blocker in the CNS, and shows no direct affect on brain cholinesterase in rats. There was a decrease in serum ChE in female rats at toxic doses (50% and 49% at 13.7 and 37.3 mg/kg/day, respectively) but RBC and brain ChE remain unaffected (males also unaffected). These apparent effects on ChE are inconsistent, occur only at high doses and are likely secondary to systemic toxicity." [quote from Cal DPR, 2008].

Cal DPR (2008) reviewed a dietary developmental neurotoxicity study by Gilmore et al. (2006) that covered a key data gap in previous risk assessments of endosulfan:

"Endosulfan technical (99.1% pure) was fed in diet to mated female Wistar rats (30/dose) at 0, 50, 150 or 400 ppm (0, 3.74, 10.8, and 29.8 mg/kg/day) from gestation day (GD) 6 through lactation day (LD) 21 (Gilmore et al., 2006). The concentration of endosulfan in the dietary preparations was adjusted to the expected food consumption during the lactation period in order to maintain a reasonably constant level of test material consumption. Offspring from 23 litters in the control, 50 and 150 ppm groups and pups from 21 litters in the 400 ppm groups were assessed neurologically up to 75 days post-natal in the functional observational battery (FOB), measurement of motor activity, auditory startle response, passive avoidance learning and memory and water maze learning and memory assessments. The motility, numbers and morphology of sperm from male pups were evaluated. The neuropathologic examination and morphometric analysis of selected neurological tissues from the pups were performed. The mean body weight of the dams was decreased in a dose-related manner during gestation. This effect persisted through the lactation period with the mean body weights of the dams at 150 and 400 ppm significantly less than that of the controls through LD 7. The mean food consumption was likewise affected for all of the treatment groups during gestation. The report stated that the decrease in food consumption, while transitional, was likely due to palatability. The treatment did not affect the gestation of the fetuses. The mean body weights of the pups in all of the treatment groups during lactation were decreased but there was no treatment-related effect on the live birth, viability or lactation indices. For the developmental landmarks, the preputial

separation was marginally delayed (4-5%) for the male pups at 150 and 400 ppm (0 = 44.9 days; 50 = 44.8 d; 150 = 47.1 d; 400 = 46.8 d). The time to vaginal opening for the female pups was not affected in a dose-related manner. Sperm motility, count and morphology of the male pups were not affected by the treatment. No treatment-related effects were noted in the FOB for either the dams or the pups. The motor activity assessment of the pups did not reveal any treatment-related effects. The auditory startle response, passive avoidance learning and memory and water maze learning and memory assessments did not indicate any treatment-related effects on the pups. No neuropathological lesions were noted in either the 21-day old pups or the 70-day old adults. Morphometric analysis of the brain of these animals did not demonstrate any treatment-related effects. The maternal NOEL was less than 3.74 mg/kg/day, based upon lower mean body weights (5 - 6%) and lower food consumption (12%) at 3.74 mg/kg/day. While these decreases are marginal, the trend is dose-related and therefore considered to be a treatment-related effect. The developmental NOEL was less than 3.74 mg/kg/day based upon the lower mean body weights (8% on post-partum day 11 only) of the offspring at 50 ppm. Body weight gain for pups was also decreased on post-partum day 11, however this effect was reversed. The developmental neurotoxicity NOEL was 29.8 mg/kg/day, based upon the lack of neurological effects in the offspring at the highest dose tested. This study was acceptable." [quote from Cal DPR, 2008].

The Agency's own review of Gilmore et al. (2006) concurred with Cal DPR's conclusions, noting particularly:

- The dams were offered treated feed from gestation day 6 and during lactation, exposing the pups *in utero* and via milk – the only observed developmental effects (delays) occurred with signs of maternal toxicity;
- The motility, count and morphology of sperm from the male pups was assessed – no treatment-associated effects were noted;
- Endosulfan was not a developmental neurotoxicant in this test.

Endocrine disruption

The potential for endosulfan to cause endocrine disruption has been widely reported. This interest is due in part because any such effects could give insight to the mechanisms of action resulting in other toxicological endpoints. Such endpoints could include reproductive and developmental toxicity, carcinogenicity, and mutagenicity / genotoxicity. Conversely, the demonstrated neurotoxicity of endosulfan could result in some or any putative endocrine disruption.

"The OECD (1998) defines an endocrine disruptor as "an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations. A potential endocrine disruptor is an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or it progeny or (sub)populations"" [quote from APVMA, 2005].

Recent regulatory reviews that examined in some depth the putative endocrine disruptive effects of endosulfan differed in their conclusions as a result of the differences in their working definitions of what constitutes an endocrine disruptor. The two approaches may be termed the American and the Australian.

American working definition

The working definition used in the final report of the US EPA Endocrine Disruptor Screening and Testing Advisory Committee (1998) for an endocrine disruptor is "an exogenous chemical or mixture that alters the structure or function(s) of the endocrine system and causes adverse effects at the level of the organism, its progeny, populations or subpopulations of organisms, based on scientific principles, data, weight-of-evidence, and the precautionary principle". The National Research Council of the USA has adopted the term *hormonally active agents*, in place of the term *endocrine disruptor chemicals* (1999) [APVMA, 2005].

The US EPA (2002) review concluded on the putative endocrine disruption potential:

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

The Cal DPR (2008) review concluded on the putative endocrine disruption potential:

> *"Although endosulfan has effects in the male reproductive system as has been described in this document, doses that would protect for neurotoxicity and other systemic effects would also protect for endocrine disruption (observed only at higher doses). The USEPA has revised their position on endosulfan as an endocrine disruptor and on the use of FQPA [Food Quality Protection Act] safety factors such that the FQPA SF for endosulfan is currently equal to 1 (USEPA, 2007). Additionally, while there were no inhalation studies performed where fetuses, pups or neonates were exposed, all data from the acceptable rat inhalation study indicated that young adolescent/adults (age 7-9 week) show systemic toxicity in the absence of histopathological effects to any reproductive organs in either sex. The No Observed Effect Level (NOEL) for inhalation (0.194 mg/kg/day) is considered protective of all age groups and data do not warrant the use of additional uncertainty factors at this time [Cal DPR, 2008]."*

"Uncertainty associated with the data gaps has been addressed with the submission of the USEPA-requested studies (subchronic neurotoxicity & DNT [Developmental Neurotoxicity] studies—both dietary). The concern for endosulfan-induced adverse developmental effects in male offspring in utero or via milk was alleviated by the DNT study. No effects to F1 sperm parameters or neurotoxicity occurred in the DNT study at doses up to 29.8 mg/kg/day [Cal DPR, 2008].

There was no quantitative or qualitative evidence of increased susceptibility to fetuses, neonates or adolescents following in utero or neonatal exposures of rats or rabbits to endosulfan during gestation or throughout reproduction cycles. The USEPA does not maintain the need for an FQPA safety factor (FQPA = 1x; USEPA, 2007) [Cal DPR, 2008]."

Australian working definition

Australian agencies consider that endocrine disruption is not considered to be an adverse end-point *per se*, but rather is a mode or mechanism of action potentially leading to other toxicological or eco-toxicological outcomes, for example, reproductive, developmental, carcinogenic or ecological effects [APVMA, 2005].

The APVMA (2005) review concluded on the putative endocrine disruption potential:

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

Agency assessment:

The essential difference between the two approaches is that the APVMA report suggests that endosulfan does not appear to be an endocrine disruptor in mammals, whereas the US EPA proposes that the weight of evidence from all studies supports the designation of endosulfan as a potential endocrine disruptor.

In the APVMA, US EPA and Cal DPR risk assessments, it has been concluded that endosulfan has not been proven to be an endocrine disruptor in humans; and, the appropriate NOAELs set for neurotoxicological effects are protective for all other adverse health effects in all human (sub)populations.

Under the HSNO framework there is no definition or a classification category specifically for endocrine disruptors, therefore endocrine disruption is considered to be a mode of action rather than an effect. A specific adverse health effect needs to be shown before a HSNO classification can be applied.

Endosulfan formulations (6.6, 6.7, 6.8 and 6.9)

The conclusion that endosulfan does not trigger mutagenicity (6.6), carcinogenicity (6.7) or reproductive/developmental toxicity (6.8), means that the formulations of endosulfan do not trigger these classifications, except for Substance A and D for which other components of the mixture trigger reproductive/developmental toxicity (6.8).

For all the endosulfan formulations, target organ systemic toxicity (6.9A) is triggered by the endosulfan based on the 6.9A classification from oral (dietary) studies.

Endosulfan sulphate

Various studies have indicated that endosulfan sulphate is the only metabolite to result in mammal tissues at significant levels (Deema et al., 1966; Gupta, 1978 in Cal DPR, 2008 p31&33).

Like endosulfan, its metabolites were more or less toxic [oral LD_{50}] according to the vehicle used and the species exposed. In general, the toxicity of the lactone and sulfate metabolites was similar to or less than that of the parent compound, while the hydroether, ether, and, in particular, the diol were far less toxic. The clinical signs of poisoning were similar to those induced by the parent compound and included piloerection, salivation, hyperactivity, respiratory distress, diarrhoea, tremors, hunching, and convulsions (JMPR, 1998).

Dorough et al. (1978 in Cal DPR, 2008) indicated that endosulfan sulfate, the main metabolite, contributes to the acute endosulfan neurotoxicity, manifested by clonic convulsions in rats. [Cal DPR, 2008 p85].

Bajpayee et al. (2006 in Cal DPR, 2008) assayed an isomeric mixture of α- and β-endosulfan, and endosulfan metabolites (including sulphate) for potential to induce DNA damage in Chinese hamster ovary (CHO) cells and human lymphocytes using the Comet assay. They were also assayed with *Salmonella typhimurium* strains TA98, TA97a, TA102, TA104 and TA100 (+/- S9 metabolic activation) for mutagenic potential. The authors reported that all compounds induced statistically significant ($p < 0.01$) dose-related increases in DNA damage in both CHO cells and in human lymphocytes. The tested compounds also were mutagenic with the *S. typhiurium* strains ($p < 0.05$), primarily TA98. [Cal DPR, 2008 p69] The sulphate was not noted as being more effective than the isomeric mixture.

In the 2008 reassessment, Cal DPR concluded that:

> *"The acute and chronic commodity endosulfan values were not modified using any type of toxicological equivalency factor (TEF) method applied to the endosulfan α-, β - or sulfate forms separately because of their same relative toxicity [Cal DPR, 2008 p175]"*

The New Zealand MRL residue definition is for the sum of α- and β-endosulfan plus endosulfan sulphate, reflecting that the toxicity of endosulfan sulphate is considered to be similar to that of the parent isomers.

The Agency concurs that: as endosulfan sulphate is the primary metabolite in mammals, its toxicity has been adequately evaluated in the submitted regulatory toxicity studies on endosulfan technical; and, specific studies using endosulfan sulphate indicate that the metabolite appears no more toxic than the parent isomers.

Endosulfan residue burdens

Submitter(s) included a number of papers reporting levels of endosulfan residues found in various human matrices (blood, adipose, etc.) (Cerrillo et al., 2006; Torres et al., 2006; Bouvier et al., 2006; Lopez-Espinosa et al., 2007; Lino et al., 2006; Botella et al., 2004; Sanghi et al., 2003 ; Shen et al., 2007; Cerrillo et al., 2005; Campoy et al., 2001a; Burke et al., 2003; Campoy et al., 2001b; Fukata et al., 2005; Carreno et al., 2007; Hernandez et al., 2002; Shen et al., 2008; Arrebola et al., 2001; Cooper et al., 2001). The presence of residues is not, *per se* an adverse health effect under the scope of the HSNO Act.

Several submitted papers did try to link endosulfan exposure to an adverse health effect, but each was deficient: for example, were unable to show causality due to multiple chemical exposures (Damgaard et al., 2006; Martinez Vidal et al., 2002; Younglai et al., 2002).

Appendix B – Environmental hazard profile

Aquatic Toxicity

The ANZECC (2000) acute toxicity database was used by the Agency to derive HC_5 values (concentrations at which the acute toxicity LC_{50}/EC_{50} is exceeded for 95% of species tested). The data are tabulated below. The data are also shown plotted as acute toxicity species sensitivity distributions for fish (freshwater and marine) and crustacea (freshwater and marine) and a combination of acute toxicity data for all species.

The Agency used these data to determine HC_5 values for those higher taxa/compartment combinations (fish/marine, fish/freshwater, crustacea/marine, crustacea/freshwater) with more than 8 species. The BurrliOZ software of ANZECC (2000) was used to determine which particular Burr Type III statistical distribution best fits the data. The software calculates the HC_5 from the distribution. Prior to calculating HC_5 values, the Agency excluded all data in which the toxicity value exceeded a water solubility of 0.33 mg/l and calculated a geometric mean where there was more than one datum for a species.

A summary of the ANZECC (2000) chronic toxicity database is also shown.

Table B1: Aquatic toxicity data (after ANZECC, 2000)

Taxon	Species	Medium	Test Type	Duration(h)	Endpoint	Effect	Ecotoxicity value[27] (µg/l)	# tests (<LoS[28])	# tests (all)
Fish	*Anabas testudineus*	Freshwater	Acute	48	LC_{50}	MORT	1.63	3	3
Fish	*Anguilla anguilla*	Freshwater	Acute	48	LC_{50}	MORT	34.04	18	18
Fish	*Barbus conchonius*	Freshwater	Acute	48	LC_{50}	MORT	21.36	1	1
Fish	*Barbus sophore*	Freshwater	Acute	48	LC_{50}	MORT	1.09	4	4
Fish	*Barbus stigma*	Freshwater	Acute	96	LC_{50}	MORT	1.93	1	1
Fish	*Bidyanus bidyanus*	Freshwater	Acute	96	LC_{50}	MORT	2.35	2	2
Fish	*Caridina weberi*	Freshwater	Acute	48	LC_{50}	MORT	10.56	12	12
Fish	*Catla catla*	Freshwater	Acute	48	LC_{50}	MORT	1.67	6	9
Fish	*Channa gachua*	Freshwater	Acute	48	LC_{50}	MORT	9.16	12	12
Fish	*Channa punctatus*	Freshwater	Acute	48	LC_{50}	MORT	6.18	10	11
Fish	*Cirrhinus mrigala*	Freshwater	Acute	96	LC_{50}	MORT	2.50	1	1
Fish	*Clarias batrachus*	Freshwater	Acute	48	LC_{50}	MORT	7.30	8	8
Fish	*Cyprinus carpio*	Freshwater	Acute	48	LC_{50}	MORT	2.47	9	9
Fish	*Cyprinus carpio carpio*	Freshwater	Acute	48	LC_{50}	MORT	33.60	1	1
Fish	*Cyprinus carpio*	Freshwater	Acute	96	LC_{50}	MORT	5.20	1	1
Fish	*Gambusia holbrooki*	Freshwater	Acute	48	LC_{50}	MORT	3.46	18	18
Fish	*Gambusia patruelis*	Freshwater	Acute	48	LC_{50}	MORT	63.00	1	1
Fish	*Gasterosteus aculeatus*	Freshwater	Acute	48	LC_{50}	MORT	6.00	1	1
Fish	*Heteropneustes fossilis*	Freshwater	Acute	48	LC_{50}	MORT	9.45	36	36
Fish	*Hypseleotris galii*	Freshwater	Acute	96	LC_{50}	MORT	2.20	1	1
Fish	*Ictalurus punctatus*	Freshwater	Acute	96	LC_{50}	MORT	1.50	2	2
Fish	*Labeo rohita*	Freshwater	Acute	96	LC_{50}	MORT	1.17	2	2
Fish	*Lepidocephalus thermalis*	Freshwater	Acute	96	LC_{50}	MORT	30.00	1	1

[27] Ecotoxicity value is the geometric mean of test results on each species excluding those that are greater than the water solubility (0.33 µg/l)

[28] LoS – limit of solubility

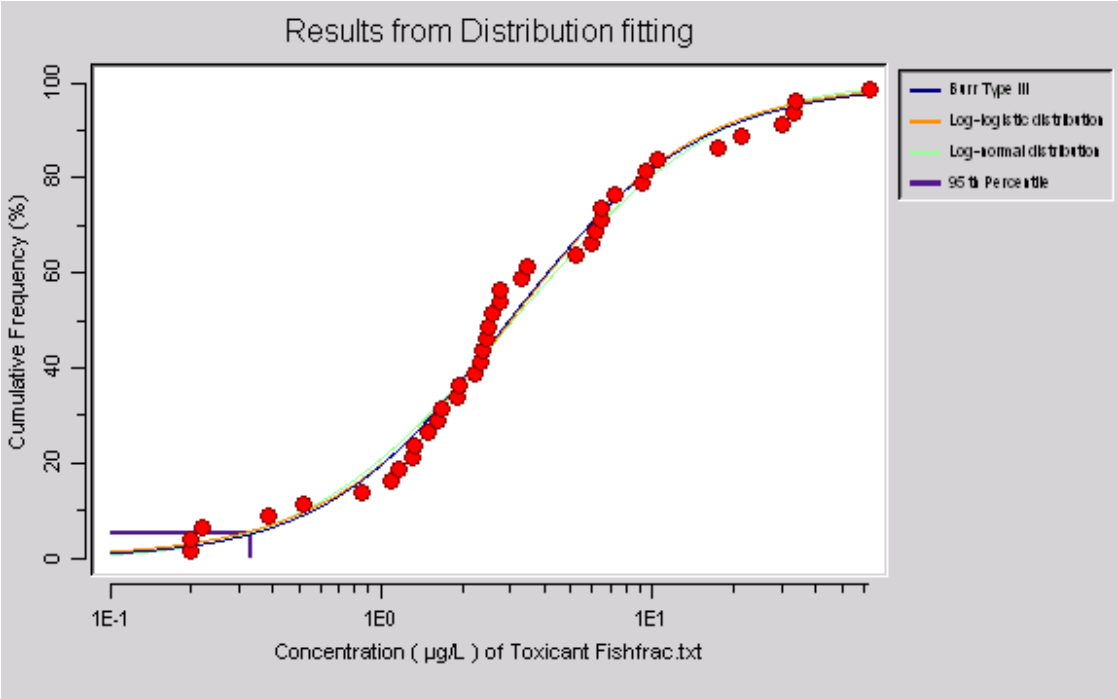
Taxon	Species	Medium	Test Type	Duration(h)	Endpoint	Effect	Ecotoxicity value[27] (µg/l)	# tests (<LoS[28])	# tests (all)
Fish	*Lepomis macrochirus*	Freshwater	Acute	48	LC_{50}	MORT	3.32	13	13
Fish	*Macquaria ambigua*	Freshwater	Acute	96	LC_{50}	MORT	0.39	2	2
Fish	*Melanotaenia duboulayi*	Freshwater	Acute	96	LC_{50}	MORT	2.57	5	5
Fish	*Morone saxatilis*	Freshwater	Acute	96	LC_{50}	MORT	0.22	7	7
Fish	*Mystus cavasius*	Freshwater	Acute	96	LC_{50}	MORT	1.90	1	1
Fish	*Mystus vittatus*	Freshwater	Acute	48	LC_{50}	MORT	0.52	3	3
Fish	*Nematolosa erebi*	Freshwater	Acute	96	LC_{50}	MORT	0.20	1	1
Fish	*Nuria danrica*	Freshwater	Acute	48	LC_{50}	MORT	17.49	2	2
Fish	*Oncorhynchus mykiss*	Freshwater	Acute	48	LC_{50}	MORT	0.85	56	56
Fish	*Oreochromis aureus*	Freshwater	Acute	96	LC_{50}	MORT	2.75	2	2
Fish	*Pimephales promelas*	Freshwater	Acute	48	LC_{50}	MORT	1.31	37	37
Fish	*Poecilia reticulata*	Freshwater	Acute	48	LC_{50}	MORT	6.49	5	5
Fish	*Rasbora sp*	Freshwater	Acute	96	LC_{50}	MORT	0.20	2	2
Fish	*Tilapia aurea*	Freshwater	Acute	72	LC_{50}	MORT	2.73	14	14
Fish	*Tilapia mossambica*	Freshwater	Acute	48	LC_{50}	MORT	6.49	17	17
Fish	*Tilapia nilotica*	Freshwater	Acute	48	LC_{50}	MORT	2.32	2	2
Fish	*Tilapia zillii*	Freshwater	Acute	48	LC_{50}	MORT	1.33	2	2
crustacea	*Alonella sp*	Freshwater	Acute	48	LC_{50}	MORT	0.20	2	2
crustacea	*Barytelphusa guerini*	Freshwater	Acute	96	LC_{50}	MORT			1
crustacea	*Caridinides sp*	Freshwater	Acute	48	EC_{50}	IMM	3.97	3	3
crustacea	*Ceriodaphnia dubia*	Freshwater	Acute	48	EC_{50}	IMM	161.00	1	3
crustacea	*Cypria sp*	Freshwater	Acute	48	LC_{50}	MORT	0.90	2	2
crustacea	*Daphnia carinata*	Freshwater	Acute	48	EC_{50}	IMM	180.00	1	2
crustacea	*Daphnia longispina*	Freshwater	Acute	48	LC_{50}	MORT	0.30	1	1
crustacea	*Daphnia magna*	Freshwater	Acute	48	EC_{50}	IMM	188.22	28	46
crustacea	*Diaptomus sp*	Freshwater	Acute	48	LC_{50}	MORT	0.60	2	2
crustacea	*Eucyclops sp*	Freshwater	Acute	48	LC_{50}	MORT	0.10	2	2

Taxon	Species	Medium	Test Type	Duration(h)	Endpoint	Effect	Ecotoxicity value[27] (µg/l)	# tests (<LoS[28])	# tests (all)
crustacea	*Gammarus lacustris*	Freshwater	Acute	48	LC_{50}	MORT	5.94	4	4
crustacea	*Macrobrachium*	Freshwater	Acute	48	LC_{50}	MORT	4.71	3	3
crustacea	*Macrobrachium lamarrei*	Freshwater	Acute	48	LC_{50}	MORT	3.89	3	3
crustacea	*Macrobrachium*	Freshwater	Acute	48	LC_{50}	MORT	6.24	4	4
crustacea	*Moinodaphnia macleayi*	Freshwater	Acute	48	EC_{50}	IMM	215.00	1	1
crustacea	*Oziotelphusa senex senex*	Freshwater	Acute	48	LC_{50}	MORT			13
crustacea	*Paratelphusa*	Freshwater	Acute	48	LC_{50}	MORT	0.22	3	3
crustacea	*Paratya australiensis*	Freshwater	Acute	48	EC_{50}	IMM	9.47	6	6
crustacea	*Potamonautes sp*	Freshwater	Acute	48	LC_{50}	MORT			1
crustacea	*Procambarus clarki*	Freshwater	Acute	96	LC_{50}	MORT	24.00	1	2
crustacea	*Enallagma sp*	Freshwater	Acute	48	LC_{50}	MORT	19.17	2	2
crustacea	*Notonecta sp*	Freshwater	Acute	48	EC_{50}	IMM	0.72	2	2
crustacea	*Pteronarcys californica*	Freshwater	Acute	48	LC_{50}	MORT	3.09	3	3
crustacea	*Sigara alternata*	Freshwater	Acute	48	LC_{50}	MORT	12.30	1	1
Molluscs	*Lamellidens corrianus*	Freshwater	Acute	96	LC_{50}	MORT	31.04	3	3
Molluscs	*Lamellidens marginalis*	Freshwater	Acute	96	LC_{50}	MORT	20.52	3	3
Molluscs	*Lymnaea natalensis*	Freshwater	Acute	48	LC_{50}	MORT			1
Molluscs	*Melanopsis dufouri*	Freshwater	Acute	96	LC_{50}	MORT			3
Amphibians	*Rana tigrina*	Freshwater	Acute	48	LC_{50}	MORT	1.90	2	2
Fish	*Atherinops affinis*	Marine	Acute	96	LC_{50}	MORT	1.30	1	1
Fish	*Cymatogaster aggregata*	Marine	Acute	96	LC_{50}	MORT	1.10	2	2
Fish	*Cyprinodon variegatus*	Marine	Acute	96	LC_{50}	MORT	1.38	18	18
Fish	*Fundulus heteroclitus*	Marine	Acute	96	LC_{50}	MORT	1.15	2	2
Fish	*Lagodon rhomboides*	Marine	Acute	96	LC_{50}	MORT	0.30	1	1
Fish	*Leiostomus xanthurus*	Marine	Acute	48	LC_{50}	MORT	0.26	3	3
Fish	*Menidia beryllina*	Marine	Acute	96	LC_{50}	MORT	1.50	1	1
Fish	*Morone saxatilis*	Marine	Acute	96	LC_{50}	MORT	0.10	2	2

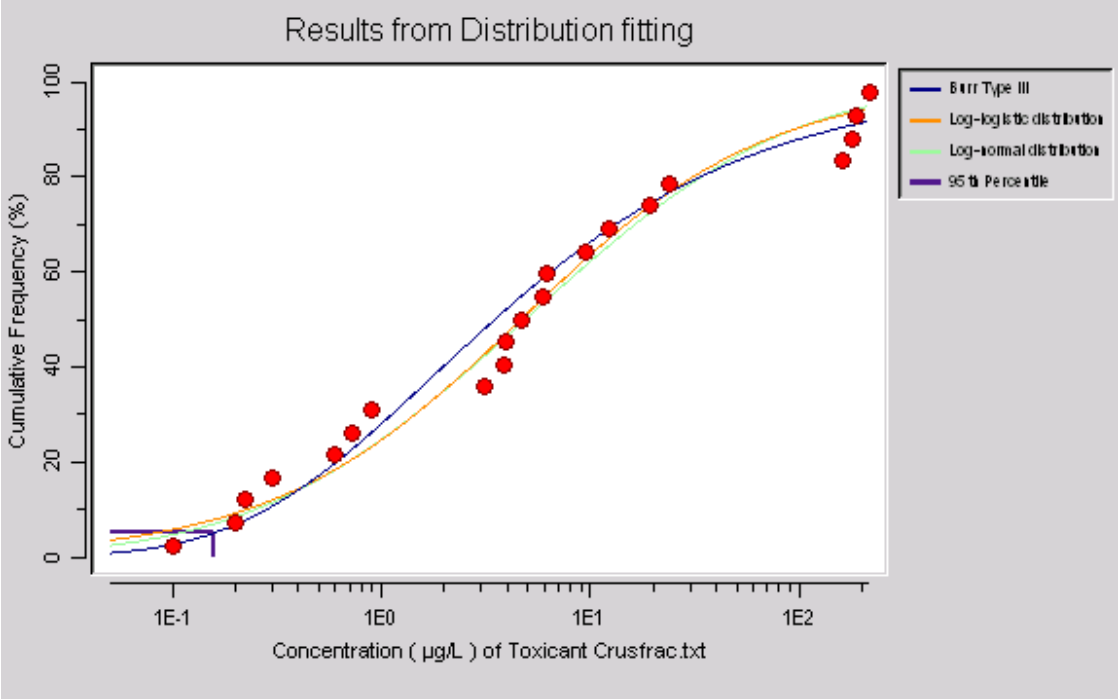
Taxon	Species	Medium	Test Type	Duration(h)	Endpoint	Effect	Ecotoxicity value[27] (µg/l)	# tests (<LoS[28])	# tests (all)
Fish	*Mugil cephalus*	Marine	Acute	48	LC_{50}	MORT	1.55	8	8
Fish	*Mugil curema*	Marine	Acute	48	LC_{50}	MORT	0.60	1	1
Fish	*Oncorhynchus kisutch*	Marine	Acute	96	LC_{50}	MORT	2.10	1	1
crustacea	*Acartia tonsa*	Marine	Acute	96	LC_{50}	MORT	0.14	6	6
crustacea	*Callinectes sapidus*	Marine	Acute	48	EC_{50}	IMM	19.67	2	2
crustacea	*Cancer magister*	Marine	Acute	96	EC_{50}	IMM	1.96	2	2
crustacea	*Crangon septemspinosa*	Marine	Acute	96	LC_{50}	MORT	0.69	3	3
crustacea	*Mysidopsis bahia*	Marine	Acute	96	LC_{50}	MORT	0.97	21	21
crustacea	*Palaemonetes pugio*	Marine	Acute	96	LC_{50}	MORT	0.80	24	24
crustacea	*Penaeus aztecus*	Marine	Acute	48	EC_{50}	IMM	0.21	2	2
crustacea	*Penaeus duorarum*	Marine	Acute	96	LC_{50}	MORT	0.17	1	1
crustacea	*Penaeus indicus*	Marine	Acute	48	LC_{50}	MORT	1.29	3	3
crustacea	*Penaeus monodon*	Marine	Acute	48	LC_{50}	MORT	17.73	5	5
crustacea	*Scylla serrata*	Marine	Acute	48	LC_{50}	MORT	92.06	2	3
Molluscs	*Crassostrea madrasensis*	Marine	Acute	48	LC_{50}	MORT	17.38	3	3
Molluscs	*Crassostrea sp.*	Marine	Acute	96	EC_{50}	GRO	65.00	1	1
Molluscs	*Crassostrea virginica*	Marine	Acute	96	EC_{50}	GRO	52.25	2	2
Molluscs	*Katelysia opima*	Marine	Acute	48	LC_{50}	MORT	15.37	3	3
Molluscs	*Meretrix casta*	Marine	Acute	48	LC_{50}	MORT	16.01	3	3
Molluscs	*Paphia laterisulca*	Marine	Acute	96	LC_{50}	MORT	1.96	1	1
Annelids	*Dinophilus gyrociliatus*	Marine	Acute	48	LC_{50}	MORT			6
Annelids	*Neanthes*	Marine	Acute	96	LC_{50}	MORT	196.60	4	4

Figure B1: Species Sensitivity Distributions of tabulated acute toxicity data (after ANZECC, 2000)

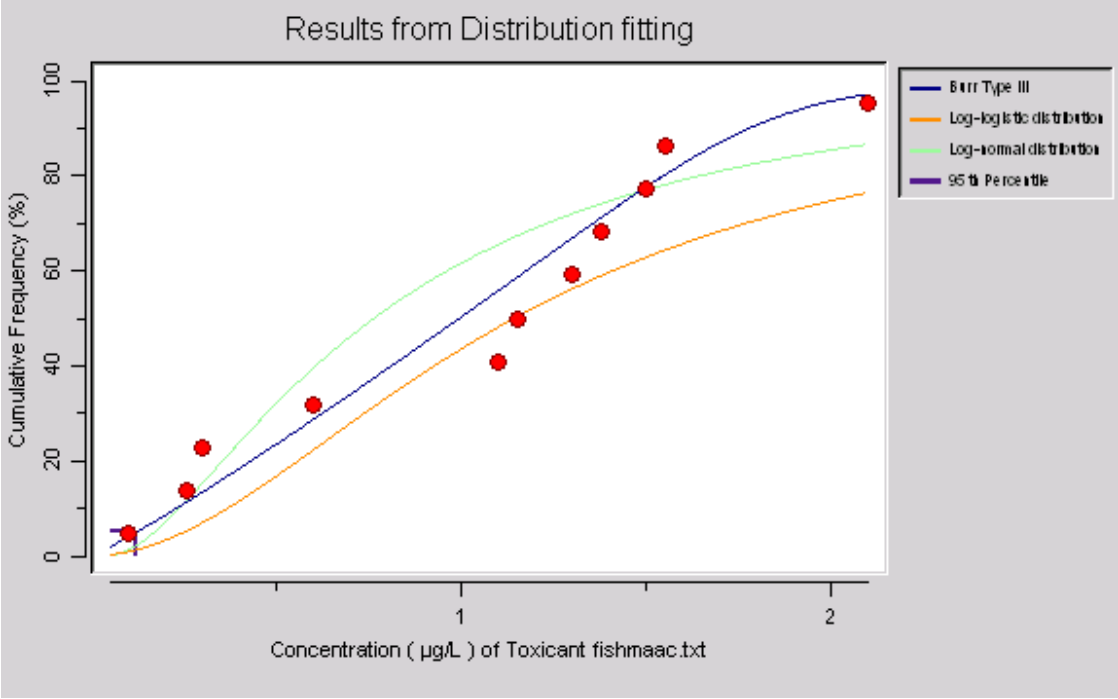
Fish, freshwater, acute



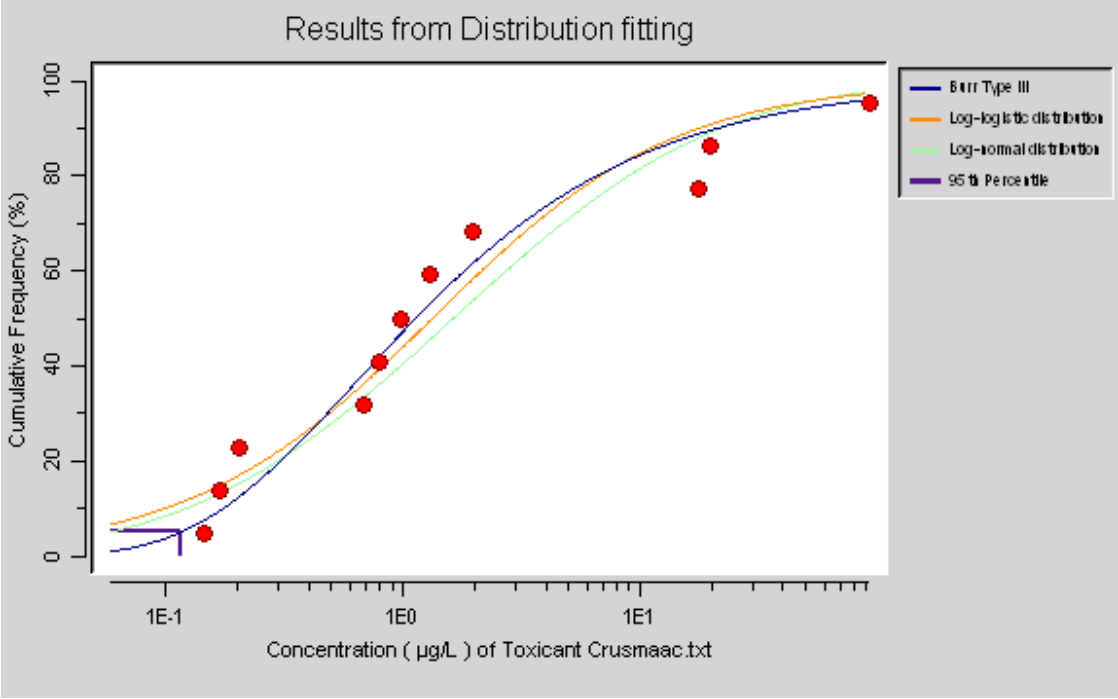
Crustacea, freshwater, acute



Fish, marine, acute



Crustacea, marine, acute



All taxa, acute

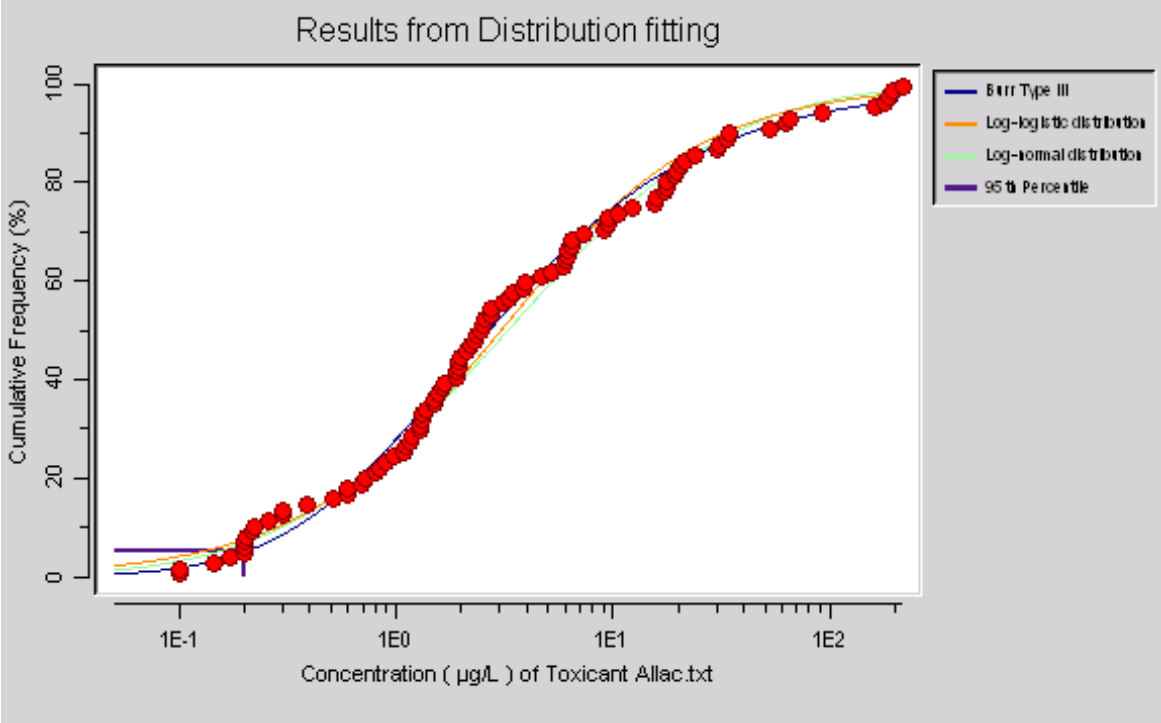


Table B2: Chronic toxicity summary of the ANZECC (2000) database

Taxon	Species	Medium	Test Type	Duration(h)	Endpoint	Effect	Ecotoxicity value[29] (µg/l)	# tests (<LoS[30])	# tests (all)
Fish	*Melanotaenia fluviatilis*	Freshwater	Chronic	144	NOEC	HAT	39.00	2	2
Fish	*Sarotherodon*	Freshwater	Chronic	1512	NOEC	REP	0.20	1	1
crustacea	*Ceriodaphnia dubia*	Freshwater	Chronic	336	NOEC	REP	10.00	1	1
crustacea	*Daphnia magna*	Freshwater	Chronic	1536	NOEC	MORT	2.70	1	1
crustacea	*Moinodaphnia macleayi*	Freshwater	Chronic	336	NOEC	REP	20.00	1	1
Green algae	*Chlorella vulgaris*	Freshwater	Chronic	336	NOEC	GRO			1
Protozoa	*Paramecium aurelia*	Freshwater	Chronic	120	NOEC	GRO	100.00	1	1
Echinoderms	*Strongylocentrotus*	Marine	Chronic	120	LC_{50}	MORT	230.00	1	1
Red algae	*Champia parvula*	Marine	Chronic	336	NOEC	REP	80.00	1	1

29 Ecotoxicity value is the geometric mean of test results on each species excluding those that are greater than the water solubility (0.33 µg/l)

30 LoS – limit of solubility

Reports of plant toxicity from USEPA ECOTOX – original documents not sourced by the Agency

Table B3: Plant toxicity as in USEPA ECOTOX database

	Lifestage treated	Duration (days)	Concentrations tested	Endpoint	Effects
Lactuca sativa	Seeds	7-14		14 d EC_{50} (germination)	> 1000 ug/g
Cajanus cajan	? spray	? harvest		NOEL (biomass)	360 g ai/ha
Lycopersicon esculentum	?	1 month	Repeat applications at 1 lb/acre	1 month NOEL (abundance)	1 lb/acre (1.14 kg/ha)
Hordeum vulgare	Seeds	1.25 days	0.05% & 0.1%	Cell damage	None
				mitotic abnormality	25% at 0.05%; 43% at 0.1%
Lagenaria siceraria	Whole plant	7 days	0.03%	General damage	27%
Cucumis sativus	Whole plant	7 days	0.03%	General damage	None
Citrullus linatus	Whole plant	7 days	0.03%	General damage	None
Ribes sp	Whole plant	28 days	0.05%	Chlorosis	None
Malus domestica	Whole plant	7 days	1.23 g/l	Photosynthesis	None
Sorghum bicolor	Whole plant	3 years	0.16-0.5 kg ai/ha, x/year	Seed yield	None (enhanced yield in 3rd year)
Brassica oleracea	Male gametophytes	7 days	50 l/ha	Sterility	18%

Non-target invertebrate toxicity

Effects concentrations used by the Agency in the non-target invertebrate risk assessment are shown in Section XXX.

Additional information is provided by Brasse (1985) and Biobest (2008) as follows:

Table B4: Test results on non-target invertebrates reported by Brasse (1985)[31]

Family	Species	Lab		Field
		Result	Exposure route	
Coccinelidae (ladybirds)	*Coccinella novemnotata* (adult)	No mortality	Directly sprayed	
	Hippodamia convergens (adult)	>50% survival after 72 h	Directly sprayed + contact	96% survival after 14 days
	Lindorus lophanthae	Low effect – oral exp	Food	
	Cryptolaemus montronzieri	Average to severe effect	Contact	
	Brumus			Adverse effect
Staphylinidae (rove beetles)	*Philonthus fuscipennis* *Tachyporus hypnorum*	Adverse effect		Adverse effect
Carabidae (ground beetles)	*Pterostichus melanarius* *Bembidion quadricmaculatum oppositum*	No effects		No effects
	Harpalus affinis	Low effect		No effect
	Amara spp (adults)	Low effect		Low effect
Chrysopidae (lacewings)	*Chrysoperla spp*			No adverse effects
	Chrysoperla carnea (larvae)	Low toxicity	Contact	
Syrphidae (hoverflies)	*Epistrophe balteata* (larvae)	100% mortality after 150-200 h	Food and contact	
	S. vitripennis (larvae)	Severe adverse effect		
Hymenoptera	*Aphelinus mali*			No adverse effects (greenhouse)

[31] Results are reported as comments as in Brasse (1985), treatment (dose and/or application rate) are not given.

Family	Species	Lab		Field
		Result	Exposure route	
	Metaphycus luteolus	Low toxicity	Oral	
	Aphytis melinus	Severe toxicity	Contact	
	Trichogramma cacoeciae *Phygadeuon trichops* *Encarsia formosa* *Coccygomimus turionellae*	Severe toxicity		
	Leptomastix dactylopii	Low toxicity		
	Apis mellifera	Toxic		Little adverse effect
Predatory mites	*Typhlodromus tiliae* *T. tiliarum* *Bryobia rubrioculus* (adult & eggs)	No or low adverse effect		
	Amblyseius fallacis	No or low adverse effects		No adverse effect
	A. potentillae	Slightly toxic		
	Typhlodromus pyri	No or low adverse effects		Increase in population, then reduction after population 7 d

Table B5: Test results on non-target invertebrates reported by Biobest (2008)

Species	Lifestage	Toxicity classification[32]
Amblyseius californicus	Nymph/Adult	slightly toxic
Amblyseius cucumeris	Nymph/Adult	toxic
Amblyseius degenerans	Nymph/Adult	toxic
Amblyseius swirskii	Nymph/Adult	
Anthocoris nemoralis	Adult	moderately toxic
Aphidius ssp.	Adult	toxic
Aphidoletes aphidimyza / Therodiplosis persicae	Adult	toxic
Bombus spp	Colony	Not compatible
Chrysopa carnea	Adult	toxic
Coleoptera	Adult	toxic
	Larva	moderately toxic
Dacnusa sibirica / Diglyphus isaea	Adult	toxic
	Larva	slightly toxic
Encarsia formosa	Adult	toxic
	Larva	non-toxic
Eretmocerus ssp.	Adult	slightly toxic
	Larva	non-toxic
Hypoaspis miles & H. aculeifer	Nymph/Adult	moderately toxic
Macrolophus caliginosus	Adult	toxic
	Nymph	toxic
Orius insidiosus / Orius laevigatus	Adult	toxic
	Nymph	moderately toxic
Paecilomyces fumosoroseus		non-toxic
Phytoseiulus persimilis	Nymph/Adult	toxic

[32] Treatment (dose) unknown, but stated that list is based on Western European horticultural and climatic conditions. Non-toxic, <25% death; Slightly toxic, 25-50% death; Moderately toxic, 50-75% death; Toxic, >75% death

Appendix C – Monitoring studies examined by the Agency

Table C1: Summary of monitoring studies examined by the Agency

Matrix	Where	Metabolites included	Concentration	Number samples	Local endosulfan use	Reference
air	North America	α & β	Up to 158 pg/m3	Many	Highest concentrations found in major fruit-growing area.	Shen et al 2005
rain	Newfoundland, New Brunswick, Nova Scotia	α & β	1.2-3.8 ng/l (median)	4 sites; 28-241 samples	Unknown. 3 of 4 sites in National Parks assumed to have no endosulfan usage. One site at least has no cultivation in the State.	Brun et al 2007
rain	Great lakes	α & β & sulphate	1.2 ng/l (geomean, 1 site), other sites only shown in figure	5 sites; approx monthly sampling	Unknown. Distance to use sites not recorded, but stated that concentrations generally higher at closer sites.	Carlson et al (2004)
rain	'Remote mountain sites' in Alps, Pyrenees and Caledonian Mtns (Norway)	α & β & sulphate	0.2-340 ng/m2/month2	3 sites; sampled up to 24 x over 2 years	Unknown. Deposition highest in Southern European sites, reflecting usage pattern.	Carrera et al 2002
rain	Great lakes	α & β	Mostly 1-10 ng/l	7 sites	Unknown. Distance to use sites not recorded, but stated that concentrations generally higher at closer sites.	Sun et al 2006
Ice	Antarctica	α & β, sulphate, ether & lactone	0.3 µg/l (ice)	1	Presumed to be none	Deger et al 2003
River water	India	?	114 +/-20 ng/l	20	Unknown. River receives large volume of domestic and industrial waste.	Aleem & Malik 2005
Runoff water	Australia	α-, β- & sulphate	2.5-45 µg/l	671 water 782 soil 58 sediment	Samples from cotton fields to which endosulfan applied 3 or 4x at 0.75 kg a.i./ha	Kennedy et al (2001)

Matrix	Where	Metabolites included	Concentration	Number samples	Local endosulfan use	Reference
Surface water	Australia	α-, β- & sulphate	0.05-0.1 µg/l with higher peaks up to about 1.5 µg/l	?	Cotton growing district, location of sample points in relation to application areas not given.	Raupach et al 2001
Surface water sediment	Uluabat lake, Turkey	Endosulfan α & β	ND-51.4 µg/l (water) 107.8 ng/g (sediment)	6 sites; 5 samples	Unknown. Agricultural area. Sites selected with high sedimentation or industrial activity.	Barlas et al 2006
Surface water groundwater	Various river basins in Portugal	α & β	0.36 µg/l (max water) Not detected (groundwater)	Various rivers	Unknown, but stated to be agricultural areas.	Cerejeira et al 2003
Marine sediment	Hugli estuary, India	Endosulfan α & sulphate	ND-0.4 ug/g dw	30 sampling occasions	Unknown – estuary receives untreated sewage, industrial effluents mining & agricultural runoff	Bhattacharya et al 2003
Marine sediment	Alexandria harbour, Egypt	?	<0.25-22 ng/g dw	23	Unknown. Sampling from areas with freshwater and wastewater input and 'pristine' areas.	Barakat et al 2002
Suspended solids	Lourens River estuary, South Africa	α & β & sulphate	18.6 ug/kg (90 %ile)	Every 14 d for 2 years	Unknown - catchment includes vineyards, apple, pear and plum orchards with application rates of 158 kg/ha [sic].	Bollmohr et al (2007)
Suspended particles & sediment	Brittany, France	α	137.5, 17.9 ug/kg dry weight, 14 non-detects	16 sites	Streams adjacent to agricultural production, but use of endosulfan unknown.	Schafer et al 2007
groundwater soil	Morocco	Yes	0.006-0.2 µg/l 5.7 ug/g dw (avg)	6 sites; # samples unknown	Agricultural area (strawberries, potatoes, industrial tomatoes, citrus fruits, groundnuts, sugar cane). Endosulfan use unknown.	El Bakouri 2007
Lake water Lake sediment Prawns	Prawn farms in coastal lake, India	?	99 ng/l (max - water) 90-238 ug/g dw (sediment) 28 ug/g ww (max prawns)	6	Endosulfan used directly in prawn ponds. Lake receives industrial effluents, sewage and agricultural waste.	Amaranemi 2006

Matrix	Where	Metabolites included	Concentration	Number samples	Local endosulfan use	Reference
Precipitation & sediment	Rocky Mountain & Glacier NP, North America		Up to 2.5 ng/l (snow) 0 to 0.44 ug/kg (sediment)	16 sites (precipitation) 21 sites (sediment)	Not locally. Distance to use sites not recorded.	Mast et al 2007
Fish	Mar Chiquita coastal lagoon, Argentina	α & β & sulphate	1-14 ng/g wet weight for different tissues	?	Sampling site is nature reserve, endosulfan use unrestricted in Argentina,	Menone et al 2000
Elephant seal blubber	Elephant Island, Antarctic peninsula	α & β & sulphate	0.9, 2.0, 2.7, 3.0 ng/g lipid (pups, juveniles, adult females, adult subdominant males respectively)	66 animals	Presumed not locally. Distance to use sites not recorded.	Miranda-Filho et al, 2007
Bark	32 countries incl 3 sites in New Zealand		10-100 ng/g lipid		Unknown	Simonich & Hites 1995
Bark	32 countries, 6 samples from New Zealand		42 ng/g lipid (avg)		Unknown	Simonich & Hites, 1997

Appendix D – Tier II modelling of aquatic risks

No Tier II modelling has been performed to reflect New Zealand conditions and use patterns.

The Agency has reviewed two Tier II analyses of aquatic risk, one from the USEPA (USEPA, 2007c) and one from Makhteshim (Ramanarayanan et al 1999), both of which relate to the use of endosulfan in the US. There are significant differences between the use patterns used in these analyses and those used in New Zealand.

Tier II modelling is normally a refinement of Tier I and is performed to clarify the conclusions of the more conservative Tier I model. In this context, the use scenario to which Tier II modelling is applied should be the same as that analysed in Tier I. In this application, Tier I and II analyses are not available for New Zealand use and conditions and a direct comparison of Tier I and II analyses must therefore be made with appropriate caution.

Nevertheless, a comparison of the outcomes with those from the Tier I analysis performed for New Zealand is instructive, and helps to position the Tier 1 modelling performed by the Agency.

USEPA

USEPA (2007c) use PRZM/EXAMS to model environmental concentrations resulting from surface runoff and leaching to groundwater and spraydrift. The scenarios modelled by USEPA for US use and by the Agency for New Zealand differ as shown below. Most notable are:

- GENEEC2, used by the Agency for analysis of use in New Zealand is a Tier I model which is simpler than the Tier II PRZM/EXAMS model with fewer input parameters.
- The method of application is different, giving rise to different estimates of spray drift.

Table D1: Comparison of Agency and USEPA aquatic exposure modelling inputs

	ERMA New Zealand			USEPA (2007c)
	Label	Turf	Citrus	
Model	GENEEC2 (Tier I)			PRZM/EXAMS (Tier II)
Use	Max New Zealand use in accordance with label	Max advised off-label use	Max advised off-label use	Max use in USA (tomato in Florida & strawberry in California)
Application rate (kg a.i./ha)	0.7	2.1	1.3	1.12
Application frequency/season	4	1	2	3
Application date	N/A			15 Sept & 15 Jan
Koc	10600			10600
Aerobic soil DT_{50} (days)	1336			1336

	ERMA New Zealand			USEPA (2007c)
	Label	Turf	Citrus	
Methods of application	Boom sprayer (high)	Boom sprayer (low)	Airblast	Aerial
% drift	1.2%	0.8%	9.7%	5%
	(default values for application method)			
Water solubility (mg/l)	0.33			3.3[33]
Aerobic aquatic DT_{50} (days)	19 (dissipation)			2671 (aerobic aquatic) 19 (hydrolysis)
Aqueous photolysis DT_{50}	Stable			Stable

The results of USEPA (2007c) compared to those from the Agency's prediction for New Zealand:

Table D2: Comparison of Agency and USEPA aquatic exposure concentrations

Output	Expected Environmental Concentrations (µg/l)				
	ERMA New Zealand			USEPA	
	Label	Turf	Citrus	Tomato, (first application 15 Sept)	Strawberry (first application 15 Jan)
Peak EEC	13	10	17	23	12
21 day average EEC	8.9	6.7	11.1	9.3	5.5
60 day average EEC	4.8	3.6	6	6.8	3.9

The New Zealand citrus scenario is most similar to the United States analysis in terms of use pattern, differing most significantly in a higher drift figure. Despite these differences, the output of the United States and New Zealand modelling is broadly similar.

Australia

APVMA (1998) model the effect that vapour transport could have on endosulfan concentrations in a 50 cm deep river 1 km downwind from a 1 km^2 cotton field to which endosulfan was applied. This analysis suggests that a concentration of 0.1 µg/l could be derived by vapour transport, as compared to 0.2 µg/l by runoff and 1.4 µg/l by drift. The corresponding water quality guideline is 0.03 µg/l for slightly to moderately disturbed freshwaters (ANZECC, 2000). APVMA (1998) do not give the temperature at which this analysis was performed, but it would be expected to have an influence on the relative importance of the different routes of environmental transport.

Makhteshim

Makhteshim has provided the Agency with environmental exposure modelling performed for endosulfan usage in the USA, based on a wide variety of crops/application methods and site-specific meteorological and hydrological conditions

[33] Model input is 10 times actual water solubility, in accordance with guidance for the model.

(Ramanarayanan et al 1999). These analyses take account of both 'realistic', as defined by market research, and label-specified usage patterns. The estimates also model the effect of buffer zones.

Exposure was modelled using PRZM, EXAMS and AgDrift (Ramanarayanan et al (1999). PRZM estimates the endosulfan load into a 1 ha, 2 m deep pond adjacent to a treated 10 ha field, EXAMS simulates the fate and transformations of endosulfan in the pond and AgDrift estimates off-target spray deposition. Preliminary analyses (Ramanarayanan & Allen 1999a) investigated the sensitivity of the models to input parameters and the output of this analysis was used to select conservative scenarios for the full analysis. A summary of the preliminary analysis is given in Appendix D.

In the full analysis (Ramanarayanan et al, 1999), the five major US crops were identified and, within the regions where they are grown, potentially high runoff and erodible soils were identified (Ramanarayanan & Allen, 1999b), based on the results of preliminary sensitivity analyses (Ramanarayanan & Allen, 1999a). Exposure estimates were made for each of these crop/soil scenarios:

Table D3: Exposure scenarios modelled by Ramanarayanan et al (1999)

Crop	Region	Soil
Apples	Ontario Plains and Finger Lakes (NY)	Collamer silty loam
Cucurbits (cantaloupes)	Sacramento & San Joaquin Valley (CA)	Garces silty loam
Cotton	Southern Mississippi Silty uplands (LA)	Loring silty loam
Potatoes	Central Snake River Plains (ID)	Rad silty loam
Tomatoes	South Florida Flatwoods (FL)	Pomello fine sand

Analyses were performed using both label-specified application rates and frequencies and 'realistic' application rates and frequencies as identified by market research:

Table D4: Application details modelled by Ramanarayanan et al (1999)

Scenario	Label-specified application		Realistic application	
	Rate per application lb a.i./acre (kg a.i./ha)	Applications per year	Rate per application lb a.i./acre (kg/ha)	Applications per year
Apples	1.0 (1.1)	3	1.5 (1.7)	1
Cantaloupes	1.0 (1.1)	3	1.1 (1.2)	1
Cotton	1.0 (1.1)	3	0.4 (0.45)	3
Potatoes	1.0 (1.1)	3	0.8 (0.91)	1
Tomatoes	0.5 (0.57)	6	0.75 (0.85)	1

The effects of a run-off buffer zone are not built into the PRZM model, but were included in the analysis of Ramanarayanan et al (1999) using a method developed by Waterborne International Inc. (Ramanarayanan et al, 1999). These developments have been validated in a field trial of endosulfan run-off from cotton in South Carolina (Ramanarayanan et al, 1999). The model was used to determine the effects of a 300' (90 m) buffer zone on the expected environmental concentration in a pond receiving runoff from a treated field.

The results of the AgDrift estimates of deposition on a water body separated from the treated field by buffer zones of different sizes are shown in Table D5. On the basis of these data, drift was input to the PRZM model as 0.03% for airblast applications, 0.19% for ground applications and an amount varying between 0.23% and 0.62% depending on crop for aerial application. These % drift figures compare to PRZM default values of 5% for aerial and 1% for ground applications.

Table D5: Percentage drift used in modelling by Ramanarayanan et al (1999)

Method of application	Crop	Drift to a Standard Water Body (% of applied)[1]		
		30' (9.1 m) buffer	100' (31 m) buffer	300' (91 m) buffer
Ground	Various	0.55	0.36	**0.19**
Airblast	Various	0.08	**0.03**	0.0006
Aerial	Cotton	–	–	**0.62**
	Potato	–	–	**0.23-0.25**
	Tomato	–	–	**0.48-0.52**

[1] Figures in bold represent the % drift used in estimating EEC in waterbodies.

The models enabled a probabilistic estimate of exposure concentration to be made. Such an approach estimates the probability of a concentration distribution, enabling estimation of the chance of an environmental concentration greater than a particular value. The 90% estimates were:

Table D6: Aquatic exposure estimates made by Ramanarayanan et al (1999)

Crop	Application			Runoff buffer zone (300', 91 m)[34]	90% Expected Environmental Concentration (µg/l)			
	Method	Rate (kg/ha)			Peak	96 h	21 day	90 day
Apple	Airblast	3 x 1.12	Label	No	0.25	0.17	0.075	0.028
	1 x 1.68	*Realistic*		*No*	*0.33*	*0.22*	*0.080*	*0.028*
Cantaloupe	Boom	3 x 1.12	Label	No	0.23	0.15	0.064	0.03
	1 x 1.23	*Realistic*		*No*	*0.15*	*0.049*	*0.013*	*0.003*
Cotton	Aerial	3 x 1.12	Label	No	3.5	2.4	1.2	0.49
	3 x 1.12	Label		Yes	0.89	0.59	0.27	0.13
	3 x 0.45	*Realistic*		*Yes*	*0.37*	*0.24*	*0.11*	*0.050*
Potato	Aerial	3 x 1.12	Label	No	0.68	0.48	0.22	0.10
	1 x 0.9	*Realistic*		*No*	*0.46*	*0.32*	*0.15*	*0.051*
Tomato	Aerial	6 x 0.56	Label	No	4.1	2.7	1.0	0.48
	6 x 0.56	Label		Yes	0.61	0.40	0.17	0.082
	1 x 0.84	*Realistic*		*Yes*	*0.34*	*0.22*	*0.08*	*0.03*
	Boom	6 x 0.56	Label	No	4.2	2.8	1.0	0.49
	6 x 0.56	Label		Yes	0.78	0.51	0.21	0.088
	1 x 0.84	*Realistic*		*Yes*	*0.23*	*0.15*	*0.063*	*0.026*

Summarising information in the above table, the effect of the 300' (90 m) buffer is to reduce the total endosulfan (α- and β-isomers and endosulfan sulphate) loading to the pond through runoff and erosion as follows:

Table D7: Summary of the effect of a buffer zone on aquatic exposure concentrations (as modelled by Ramanarayanan et al, 1999)

Crop	Application		% reduction in endosulfan loading		
	Method	Rate (kg/ha)	Mean	Max	Min
Cotton	Aerial	3 x 1.12	81	88	61
Tomato	Aerial	6 x 0.56	81	86	74
	Boom	6 x 0.56	85	89	70

The Agency notes that the effectiveness of any buffer zone will depend not only on its width, but its topography and vegetation cover.

In terms of use pattern (application rate and method), the apple scenario modelled by Ramanarayanan et al (1999) is most similar to the citrus scenario modelled by the Agency and the cantaloupe and tomato boom scenarios are most applicable to the Agency's 'label' scenario. The turf scenario modelled by the Agency is not comparable

[34] Although the data are presented (Ramanarayanan et al 1999, Appendix 14) as being with or without a buffer zone, the spray drift contribution to the endosulfan loading was input assuming there is a buffer zone of 300' (91 m) for boom applications, 100' (31 m) for airblast applications, and a variable size for aerial applications dependent on the crop and meteorological conditions at the time of application.

to any of Ramanarayanan et al's analyses. Values for the input parameters used by the Agency are compared to those used in the analysis of Ramanarayanan et al (1999) below:

Table D8: Comparison of Agency and Ramanarayanan et al (1999) aquatic exposure modelling inputs

	ERMA New Zealand		Ramanarayanan et al (1999)				
	Label (4x0.7 kg a.i./ha)	Citrus (2x1.3 kg a.i./ha)	Canteloupe		Tomato	Apple	
			Label (3x1.12 kg a.i./ha)	Realistic (1x1.23 kg a.i./ha)	Label (6x0.56 kg a.i./ha)	Label (3x1. 12 kg a.i./h a)	Realistic (1x1.68 kg a.i./ha)
Model	GENEEC 2		PRZM/EXAMS				
Application rate (kg a.i./ha)	0.7	1.3	1.12	1.23	0.56	1.12	1.68
Application frequency/season	4	2	3	1	6	3	1
Koc	10600		10660				
Aerobic soil DT_{50} (days)	1336		150				
Method of application	Boom (high)	Airblast	Boom			Airblast	
% drift	1.2%	9.7%	0.19%			0.03%	
Water solubility (mg/l)	0.33		0.33				
Aerobic aquatic DT_{50} (days)	19		19				
Aqueous photolysis DT_{50}	Stable		Stable				

A comparison of the output from the Agency and Ramanarayanan et al's analyses shows:

Table D9: Comparison of Agency and Ramanarayanan et al (1999) aquatic exposure estimates

	ERMA New Zealand		Ramanarayanan et al (1999)				
			Apple		Canteloupe		Tomato
	Label (4x0.7 kg a.i./ha)	Citrus (2x1.3 kg a.i./ha)	Label (3x1.1 2 kg a.i./ha)	Realistic (1x1.68 kg a.i./ha)	Label (3x1.12 kg a.i./ha)	Realistic (1x1.23 kg a.i./ha)	Label (6x0.56 kg a.i./ha)
Peak EEC	13	16	0.25	0.33	0.23	0.15	4.1
21 day average EEC	8.3	10.3	0.075	0.08	0.064	0.013	1.0
60 day average EEC	4.2	5.3	0.036	0.033	0.036	0.004	0.56

The concentrations determined by the Ramanarayanan et al (1999) analysis are lower than those determined by the Tier 1 analysis performed by the Agency. The difference in percentage drift contributes a large part of this difference, and this difference arises because of the more specific information used in AgDrift (compared to GENEEC) and because Ramanarayanan et al (1999) include a 100-300' (31-91 m) buffer zone in their estimation of drift. To relate the detail of analyses such as these to New Zealand, or to run such models for the New Zealand scenario, it would be necessary to compare hydrological and soil physical parameters to the conditions in which the chemical is used in New Zealand. The Agency has work underway to enable such a detailed analysis, but this work is insufficiently advanced to apply it to this application. For the current analysis, the Agency has merely drawn broad conclusions from the analysis of Ramanarayanan et al (1999), as follows:

- Actual use patterns may differ very significantly from label specifications. The Agency has based its assessment on label directions and also on industry estimates of actual usage rates for off-label use.
- As expected, greater use of site-specific input data, for example estimates of percentage drift, results in lower EEC values. This explains the difference between the estimates made for tomatoes in USEPA (2007c), peak EEC 23 µg/l compared to the estimates in Ramanarayanan et al (1999), peak EEC 4.1 µg/l.
- The modelling of the effects of a buffer zone indicate that a 90 m buffer zone will reduce the average endosulfan loading by more than 80% under the conditions modelled.

Appendix E – Input and results of analysis used to select worst-case sites in Ramanarayanan et al (1999)

Physicochemical input parameters used in this analysis were:

Table E1: Input parameters in modelling to select 'worst-case' scenarios (Ramanarayanan & Allen, 1999a)

Property	Value	Comment
Molecular Weight	406.9 g/mole	Product Chemistry
Vapor Pressure	1.5 x 10^{-5} Torr @ 25 C	Product Chemistry
Solubility	0.33 mg/L	Product Chemistry
Partition Coefficient	10660 cm^3/g	Weighted average of α- and β-endosulfan and endosulfan sulfate Adsorption/Desorption Studies[a]
Soil Dissipation (half-life)	150 days	Median value for degradation of α- and β-endosulfan plus endosulfan sulfate from field dissipation studies conducted in Georgia and California. This value implicitly includes aerobic soil metabolism, hydrolysis, soil photolysis, biolysis and volatilization[a]
Soil Photolysis	none	
Foliar Dissipation (half-life)	0.95 day	Mean of foliar dissipation half-life on peach leaves (includes volatilization)[a]
Foliar Washoff Rate	0.067 cm^{-1} of Precipitation	From KY cotton study[a]
Aqueous Photolysis	none	
Aerobic Sediment/Water Dissipation (half-life)	19 days	Mean half-life of combined α- and β-endosulfan and endosulfan sulfate residues in the total sediment/water system[a]

[a] Details of the derivation of these parameters are given in Ramanarayanan (1999a)

Preliminary analyses (Ramanarayanan & Allen, 1999a) were performed to determine the sensitivity of the models to specific input parameters, information that was then used to select scenarios likely to lead to high endosulfan concentrations in non-target waters. The preliminary analyses were performed using cotton grown on silty loam as an example and were performed for years representing the median and 90 percentile rainfall. The input parameters investigated were:

- For PRZM seven hydrological and physical parameters and four compound specific parameters
- For EXAMS, partition coefficient, degradation rate and the proportion of sorbed sediment sinking to the benthic zone (PRBEN).
- For AgDrift, the meteorological parameters, wind speed, temperature and humidity.

The results showed:

- Using PRZM, the endosulfan loading to the surface water bodies is more sensitive to hydrological and soil physical parameters than the properties of endosulfan.

This emphasises the need for information on regional/local conditions to draw firm conclusions from higher tier modelling.

- Using EXAMS, the dissolved and sorbed sediment concentrations were most sensitive to PRBEN and least sensitive to K_{oc}.
- Using AgDrift, the deposition into a pond 300' from the edge of a treated field was sensitive to all three meteorological conditions, but particularly relative humidity.

Appendix F – Calculations underlying bird risk assessments

Calculations underlying the field feeding bird risk assessment:

Table F1: Summary of T-REX model inputs

Input Category	Label Use USEPA	Label Use Makhteshim	Off-label Use Turf USEPA	Off-label Use Turf Makhteshim	Off-label Use Citrus USEPA	Off-label Use Citrus Makhteshim
%A.I.	35	35	35	35	35	35
Application rate (lbs/Acre)	1.784	1.784	5.352	5.352	3.31	3.31
Half-life (days)	4	0.95	4	4	4	0.95
Application interval (days)	10	10	NA	NA	14	14
Number of Applications	4	4	1	1	2	2
Avian LD_{50} (mg.kg bw)	28	28	28	28	28	28
Avian LC_{50} (mg.kg diet)	805	805	805	805	805	805
Avian LD_{50} (mg.kg bw)	30	30	30	30	30	30
Mineau scaling factor	1.15	1.15	1.15	1.15	1.15	1.15
Application type	Broadcast	Broadcast	Broadcast	Broadcast	Broadcast	Broadcast
Product physical form	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid
Fluid ounces product/Acre	25.33	25.33	76.00	76.00	47.05	47.05

Assumptions:

All products contain the active ingredient, endosulfan, at a concentration of 35% w/w;

Density of all products = 1.08 g/ml;

Conversion of kg/ha to lb/A = multiply by 0.892;

1 pound = 14.20 ounces (US liquid) accounting for product density;

The foliar dissipation half-life of endosulfan = 4 days (USEPA 2002);

The foliar dissipation half-life of endosulfan = 0.95 days (Makhteshim).

Table F2: Avian acute and chronic risk quotients for a single and multiple broadcast applications of endosulfan products based on a bobwhite quail LC_{50} of 805 ppm, a mallard duck NOEC of 30 ppm and a half-life of 4 days

Use Rate No. Apps. Min. Interval	Food Items	Peak EEC [c] (mg/kg)	56 day mean EEC [c] (mg/kg)	Acute RQ (EEC/LC_{50})	Chronic RQ (EEC/NOEC)	
					peak EEC/NOEC	56-day EEC/NOEC
Label Use 0.7 kg ai/ha 4 Apps. 10 days	Short Grass	181.86	65.91	0.23	6.06 [b]	2.20 [b]
	Tall Grass	83.35	30.21	0.1	2.78 [b]	1.01 [b]
	Broadleaf plants/Insects	102.30	37.07	0.13	3.41 [b]	1.24 [b]
	Seed	11.37	4.12	0.01	0.38	0.14
Off -label Use Turf 2.1 kg ai/ha 1 Apps.–days	Short Grass	449.57	49.57	0.56 [a]	14.99 [b]	1.65 [b]
	Tall Grass	206.05	22.72	0.26	6.87 [b]	0.76
	Broadleaf plants/Insects	252.88	27.88	0.31	8.43 [b]	0.93
	Seed	28.10	3.10	0.03	0.94	0.1
Off-label Use Citrus 1.3 kg ai/ha 2 Apps. 14 days	Short Grass	302.62	61.30	0.38	10.09 [b]	2.04 [b]
	Tall Grass	138.70	28.09	0.17	4.62 [b]	0.94
	Broadleaf plants/Insects	170.22	34.48	0.21	5.67 [b]	1.15 [b]
	Seed	18.91	3.83	0.02	0.63	0.13

[a] exceeds acute high LOC

[b] exceeds chronic LOC

[c] estimated environmental concentrations predicted using 1st-order degradation model based on foliar dissipation.

Table F3: Refined avian acute and chronic risk quotients for a single and multiple broadcast applications of endosulfan products based on a bobwhite quail LC_{50} of 805 ppm, a mallard duck NOEC of 30 ppm and a half-life of 0.95 days.

Use Rate No. Apps. Min. Interval	Food Items	Peak EEC [c] (mg/kg)	56 day mean EEC [c] (mg/kg)	Acute RQ (EEC/LC_{50})	Chronic RQ (EEC/NOEC)	
					peak EEC/NOEC	56-day EEC/NOEC
Label Use 0.7 kg ai/ha 4 Apps. 10 days	Short Grass	149.96	20.31	0.19	5.00 [b]	0.68
	Tall Grass	68.73	9.31	0.09	2.29 [b]	0.31
	Broadleaf plants/Insects	84.35	11.42	0.10	2.81 [b]	0.38
	Seed	9.37	1.27	0.01	0.31	0.04
Off -label Use	Short Grass	449.57	15.23	0.56 [a]	14.99 [b]	0.51
	Tall Grass	206.05	6.98	0.26	6.87 [b]	0.23

Use Rate No. Apps. Min. Interval	Food Items	Peak EEC [c] (mg/kg)	56 day mean EEC [c] (mg/kg)	Acute RQ (EEC/LC_{50})	Chronic RQ (EEC/NOEC)	
					peak EEC/NOEC	56-day EEC/NOEC
Turf 2.1 kg ai/ha 1 Apps. – days	Broadleaf plants/Insects	252.88	8.57	0.31	8.43 [b]	0.29
	Seed	28.10	0.95	0.03	0.94	0.03
Off-label Use Citrus 1.3 kg ai/ha 2 Apps. 14 days	Short Grass	278.05	18.84	0.35	9.27 [b]	0.63
	Tall Grass	127.44	8.63	0.16	4.25 [b]	0.29
	Broadleaf plants/Insects	156.40	10.60	0.19	5.21 [b]	0.35
	Seed	17.38	1.18	0.02	0.58	0.04

[a] exceeds acute high LOC

[b] exceeds chronic LOC

[c] estimated environmental concentrations predicted using 1st-order degradation model based on foliar dissipation.

Spreadsheet-based Terrestrial Exposure Values (USEPA, 2002)

A first order decay assumption is used to determine the concentration at each day after initial application based on the concentration resulting from the initial and additional applications. The decay is calculated from the first order rate equation:

$$\mathbf{C_T = C_i e^{-kT}}$$

or in log-transformed:

$$\mathbf{\ln (C_T/C_i) = -kT}$$

Where:
$\mathbf{C_T}$ = concentration at time T

$\mathbf{C_i}$ = concentration in parts per million (ppm) present initially (on day zero) on the surfaces. C*i* is calculated based on Kanega and Fletcher by multiplying the application rate, in pounds active ingredient per acre, by 240 for short grass, 110 for tall grass, and 135 for broad-leaf plants/insects and 15 for seeds. Additional applications are converted from pounds active ingredient per acre to PPM on the plant surface and the addition mass added to the mass of the chemical still present on the surfaces on the day of application.

k= degradation rate constant determined from studies of hydrolysis, photolysis, microbial degradation, etc. Since degradation rate is generally reported in terms of half-life, the rate constant is calculated from the input half-life (k = ln 2/T1/2) instead of being input directly.

Choosing which process controls the degradation rate and which half-life to use in terrestrial exposure calculations is open for debate and should be done by a qualified scientist.

T= time, in days, since the start of the simulation. The initial application is on day 0. The simulation is set to run for 365 days. The program calculates concentration on each type of surface on a daily interval for one year. The maximum concentration during the year and the average concentration during the first 56 days are calculated.

Calculations underlying aquatic feeding bird risk assessment
Body residues and equations from USEPA (2007c) used to estimate Toxicity Exposure Ratios (TER) for New Zealand birds feeding in water, are presented.

Predicted concentrations of endosulfan in aquatic organism tissues (µg/kg) at different trophic levels (Table 14 in USEPA 2007c, Attachment B). The percentile concentrations are the result of Monte Carlo simulations to derive residue distributions.

Table F4: Body residues (µg/kg) in aquatic foodweb (USEPA, 2007c)

Trophic Level	Mean	SD	25th%	75th %	90th %
Phytoplankton	1,279	1,290	383	1,739	3,233
Zooplankton	1,280	1,307	376	1,742	3,237
Benthic Invertebrates	1,282	1,271	399	1,749	3,188
Filter Feeders	1,411	1,588	407	1,857	3,476
Small Forage Fish	3,346	3,755	950	4,477	8,461
Medium Forage Fish	3,447	3,684	960	4,648	8,856
Piscivorous Fish	4,682	20,306	1,051	5,860	11,925

The Agency used the mean and 90th percentile information in the above table to estimate the exposure of aquatic-feeding birds using the following equations. Equation numbers below refer to USEPA 2007c, Attachment B.

Food ingestion rate (FI, kg dry food/kg-bw day)

Eq.A.12 $$FI = \frac{0.0582 * Wt^{0.651}}{Fw}$$

Where Wt is animal body weight (kg);
Fw is food dry weight as a proportion of wet weight (0.2 for ducks and 0.25 for heron and grebe).

Note In USEPA (2007c), the denominator in this equation is incorrectly written as Wt, rather than Fw.

Drinking water intake (DW)

*Eq.A.*14 $$DW = (0.059 * Wt^{0.67})$$

Where DW is the water intake (litre/day)

Note In USEPA (2007c), animal body weight (kg) is referred to as either Wt or BW.

Total exposure (EEC)

Eq.A.15 Dose-based exposure[35] (µg/kg-bw/day) = $\sum(\%_{prey} * C_{Bprey}) * FI + \frac{C_{WTO} * DW}{Wt}$

Where $\%_{prey}$ is the estimated proportion of the diet comprised of each food item;
C_{Bprey} is the concentration in each prey item (µg/kg; Table above);
C_{WTO} is the bioavailable concentration in the water (µg/l; assumed equivalent to the Estimated Environmental Concentration (4.8 µg/l) under New Zealand label conditions);
DW is the water intake (litre/day; from USEPA, 1993).

Eq.A.16 Dietary-based exposure (µg/day) = $\sum(\%_{prey} * C_{Bprey}) * FI * Wt + (C_{WTO} * DW)$

Estimated toxicity to New Zealand species

The toxicity of endosulfan to New Zealand species for which toxicity tests have not been performed is calculated as follows:

Dietary-based toxicity – use the available toxicity values (µg/day)
Dose-based toxicity (µg/kg-bw/day):

Eq.A.18 $AT = LD_{50}(AW/TW)^{(x-1)}$

Where AT is the adjusted toxicity value (toxicity to species for which there are no test data);
AW is the body weight of the bird (species) for which a toxicity value is to be estimated;
TW is the body weight of the bird (species) for which there are test data;
x is the Mineau scaling factor (1.15 used).

Risk Quotients

Dietary-based $\frac{\text{Dietary-based exposure (µg/day)}}{\text{Dietary-based toxicity (µg/day)}}$

Dose-based $\frac{\text{Dose-based exposure (µg/kg-bw/day)}}{\text{AT (µg/kg-bw/day)}}$

[35] USEPA (2007c) refer to this as Dose-based EEC, but for ease of understanding, the Agency prefers the term Dose-based exposure. Similarly in Eq.A.16, the Agency has substituted the USEPA term Dietary-based EEC with Dietary-based exposure.

Appendix G – Margins of exposure for re-entry to endosulfan treated crops[36]

APVMA (2005)

Table 19: MOE for various crops extrapolated from the re-entry DFR data on melons, peaches and grapes, standardised to relevant application rates and TC for the crops.

Re-entry day	MOE (Dermal absorbed dose/NOEL)							
	Melons	Peaches	Grapes	Citrus	Nut trees (Pecans)	Fruit	Vegetables, Nursery crops	Broadacre Crops (other than cotton)
	*TC:2500 (high exposure)***	*TC:3000 (high exposure)***	*TC 5000 (high exposure)****	*TC: 3000 (high exposure)***	*TC: 2500 (high exposure)***	*TC: 3000 (high exposure)***	*TC: 2500 (high exposure)***	*TC: 1500 (medium exposure)**
	Application rate: 2.1 L/ha	*Application rate: 2.1 L/ha*	*Application rate: 2.1 L/ha*	*Application rate: 2.8 L/ha*	*Application rate: 3.0 L/ha*	*Application rate: 3.0 L/ha*	*Application rate: 2.1 L/ha*	*Application rate: 2.1 L/ha*
0	564	4800	711	343	392	325	565	914
1	1280	9600	1600	800	873	914	1280	2133
3	4800	19200	4800	2743	3200	2743	4800	6400
5	6400	19200	6400	4800	4800	4800	6400	9600
7	9600	64000	19200	6400	9600	6400	9600	19200
10	19200	64000	19200	9600	9600	9600	19200	19200
14	19200	64000	9600	9600	9600	9600	19200	19200
17	19200	64000	9600	19200	19200	19200	19200	19200
21	19200	38400	19200	21333	19200	19200	19200	64000
24	19200	96000	9600	21333	19200	19200	19200	64000
28	19200	192000	<64000	21333	19200	19200	19200	64000

* irrigation, scouting, weeding mature plants
**harvesting, pruning, training, tying
***hand harvesting resulting in the greatest re-entry exposure

[36] The results here are assessed for the human health significant using margin of exposure in accordance with the overseas sources. To enable comparison with the RQ where a value >1 is acceptable, the MOE is a reciprocal expression. The MOE result must be >100 if the uncertainty factors applies are 100, or >300 if the uncertainty factors applies is 300. Several overseas Agencies used a higher uncertainty factors, 300 rather than the 100 the Agency used in deriving its AOEL and ADE. The overseas authorities have used various NOEL values, sometime a dermal NOEL in there MOE estimates.

Canada (PMRA, 2007)

Table 5 Summary of REIs for All Postpplication Activities for EC Formulations

Crop	No. of Applications	Application Rate (kg a.i./ha)	Activity	TC (cm^2/h)	REI	DFR[a] ($\mu g/cm^2$)	Dermal Exposure[b] (µg/kg bw/day)	MOE[c]
Bean	2	1	Hand harvesting	2500	12	0.035	9.82	306
			Irrigation, scouting	1500	9	0.058	9.66	311
			Scouting, thinning, hand weeding	100	0	0.875	6.31	475
Broccoli, Brussels sprouts, cabbage, cauliflower	2	0.8	Harvesting, irrigation, hand pruning (full foliage)	5000	16	0.0175	10	300
			Scouting (full foliage)	4000	14	0.022	9.73	308
			Hand weeding (full/min foliage); scouting, thinning, irrigation (minimum foliage)	2000	10	0.044	8.61	349
		0.6 (min)	Harvesting, irrigation, hand pruning (full foliage)	5000	14	0.0159	9.12	329
			Scouting (full foliage)	4000	12	0.0206	9.42	318
			Hand weeding (full/min foliage); scouting, thinning, irrigation (minimum foliage)	2000	8	0.041	9.38	320
Celery, lettuce	2	0.8	Hand harvesting	2500	11	0.035	9.13	329
			Irrigation, scouting (full foliage)	1500	8	0.058	9.38	320
			Hand weeding (full/minimum foliage); irrigation, scouting (minimum/foliage)	500	4	0.175	7.89	380
Sweet corn	1	1.7	Detasseling, hand harvesting	17000	> 22[d]	0.005	57.15	52
			Irrigation, scouting, hand weeding (full foliage)	1000	10	0.0875	9.15	328
			Scouting (low-crop height)	400	6	0.218	8.2	366
			Hand weeding	100	1	0.875	7.85	382
Cucumber, melon, pumpkin, squash	2	0.6	Hand harvesting, pruning, thinning, turning (full foliage)	2500	9	0.035	9.66	311
			Irrigation, scouting, hand weeding (full foliage)	1500	7	0.058	8.68	346
			Scouting, thinning, hand weeding (minimum foliage)	500	3	0.175	7.74	387

Crop	No. of Applications	Application Rate (kg a.i./ha)	Activity	TC (cm^2/h)	REI	DFR[a] ($\mu g/cm^2$)	Dermal Exposure[b] (µg/kg bw/day)	MOE[c]
Eggplant, pepper, field tomato	2	1.68	Hand harvesting and pruning, staking, tying (full foliage)	1000	10	0.0875	9.04	332
			Irrigation, scouting (full foliage), hand pruning (minimum)	700	8	0.125	9.2	326
			Weeding, scouting, thinning	500	6	0.175	10.13	296
		1.2	Hand harvesting and pruning, staking, tying (full foliage)	1000	8	0.0821	9.38	320
			Irrigation, scouting (full foliage), hand pruning (minimum)	700	6	0.126	10.13	296
			Weeding, scouting, thinning	500	5	0.161	9.19	327
Peas	2	0.8	Hand harvesting	2500	11	0.035	9.13	329
			Irrigation, scouting (full foliage)	1500	8	0.058	9.38	320
			Hand weeding (full foliage), scouting, thinning, irrigation (minimum foliage)	100	0	0.875	5.05	594
Potato	2	0.8	Irrigation, scouting (full foliage)	1500	8	0.058	9.38	320
			Hand weeding (full foliage), irrigation, scouting (minimum foliage)	300	2	0.291	8.22	365
Rutabaga, turnip	2	0.8	Hand harvesting	2500	11	0.035	9.13	329
			Irrigation, scouting, hand weeding (full foliage), thinning (min. foliage)	300	2	0.291	8.22	365
Sugar beet	1	1.1	Irrigation, scouting (full foliage)	1500	10	0.058	8.88	338
			Thinning, hand weeding (full foliage); irrigation, scouting (minimum foliage)	100	0	0.875	6.94	432
Strawberry	2	1.1	Hand harvesting, hand pinching, training (full foliage)	1500	10	0.058	8.88	338
			Irrigation, mulching, scouting, weeding	400	4	0.218	8.68	346
		0.5	Hand harvesting, hand pinching, training (full foliage)	1500	6	0.052	9.04	332
			Irrigation, mulching, scouting, weeding	400	1	0.201	9.23	325

Crop	No. of Applications	Application Rate (kg a.i./ha)	Activity	TC (cm^2/h)	REI	DFR[a] ($\mu g/cm^2$)	Dermal Exposure[b] (µg/kg bw/day)	MOE[c]
Ornamentals (cut flowers)	2	2.8	All	7000	> 22[d]	0.0484	38.76	77
		1.4	All	7000	> 2[d]	0.0242	19.38	155
Ornamentals (potted plants)	2	2.8	All	400	8	0.191	8.76	343
		1.4	All	400	5	0.187	8.58	350
Ornamentals (trees; Christmas trees)	1	2.8	Shaping Christmas trees	500	1	0.133	7.62	394
			Hand-line irrigations in Christmas trees	1100	3	0.08	9.43	318
		1.4	Shaping Christmas trees	500	1	0.0667	3.81	788
			Hand-line irrigations in Christmas trees	1100	1	0.0667	8.38	358
Greenhouse cucumber, tomato	1	0.75	All	1800	> 0[e]	1.215	250	12
Greenhouse pepper	1	0.6	All	1800	> 0[e]	0.972	200	15
Greenhouse lettuce	1	0.6	All	400	> 0[e]	0.972	44	68

[a] DFR calculations are based on actual data points from a study on peaches. The melon DFR calculations are based on a log-quadratic model. For greenhouse vegetables, estimated residues on day 0 are based on 20% of the application rate being dislodgeable.

[b] Dermal exposure = DFR × TC × 8 h /70 kg.

[c] Based on the short- and intermediate-term dermal NOAEL of 0.7 mg/kg/day (target MOE = 300); values in shaded cells indicate where target MOE is not met.

[d] At this day, the curve predicted by the log-quadratic equation beings to increase in value; therefore, this is the last relevant datapoint in the curve.

[e] REIs could not be established because DFR data were not provided for greenhouse crops and there is no default dissipation value for indoor crops.

California (Cal DPR, 2008)

Table 42. Estimated Margins of Exposure for Occupational and Aggregate (Occupational + Dietary) Short Term, Seasonal and Annual Endosulfan Exposure for Reentry Workers

Exposure scenario[a]	STADD MOEs[b]		SADD MOEs[b]		Mean AADD MOEs[b]	
	Occupational	Aggregate[c]	Occupational	Aggregate[c]	Occupational	Aggregate[c]
Almond, Thinning	***78***	***64***	--d	--	--	--
Broccoli, Hand Harvesting	***23***	***22***	148	144	285	263
Broccoli, Scouting	***8***	***8***	***98***	***97***	114	110
Citrus, Scouting	***39***	***35***	--	--	--	--
Sweet Corn, Hand Harvesting	***1***	***1***	***16***	***15***	***95***	***92***
Cotton, Scouting	***11***	***11***	131	108	285	263
Cucumber, Hand Harvesting	***13***	***13***	169	165	570	487
Grape, Cane Turning	***2***	***2***	***8***	***8***	***12***	***12***
Lettuce, Scouting	***4***	***4***	295	283	285	263
Ornamentals, Hand Harvesting	***78***	***64***	--	--	--	--
Peach, Thinning	***13***	***12***	***42***	***42***	114	110
Potato, Scouting	***22***	***21***	295	283	285	263
Strawberry, Hand Harvesting	***10***	***10***	--	--	--	--
Tomato, Hand Harvesting	***33***	***33***	131	129	190	180
Ornamentals, Cut Flowers, Hand Harvesting	***4***	***4***	--	--	--	--

a - Reentry exposure scenarios from Tables 23-24

b - Margin of Exposure = Critical NOEL) Exposure Dosage: Critical Acute NOEL = 0.7 mg/kg/day (Rabbit Developmental study: salivation, convulsions thrashing, noisy/rapid breathing, hyperactivity, salivation and nasal discharge). Critical Subchronic (seasonal) NOEL was 1.18 mg/kg/day based on increased relative liver and kidney weights, decreased food consumption, and decreased body weights. Critical Chronic (annual) NOEL = 0.57 mg/kg/day (Chronic Dog study: premature deaths (not spontaneous), neurotoxicity); exposure doses from Table 23-24. Values were rounded to whole integers.

c - Aggregate = aggregate occupational and dietary exposure. Acute dietary exposure = 2.06 ug/kg/day based on the 95th percentile of user-day exposure for Females (13+ years), nursing and chronic dietary exposure = 0.17 ug/kg/day (%CT; mean annual consumption for Females (13+ years)). Values were rounded to 2 significant figures.

d - NA = Not applicable.

Bold and italics indicates MOE of less than 100

Appendix H – Control measures taken overseas of relevance to New Zealand

The following discussion includes controls taken to manage risks inherent to the manufacturing of endosulfan formulations. It is noted that currently endosulfan is not manufactured or formulated in New Zealand, but the existing approvals permit such manufacturing and therefore these overseas controls are listed for completeness.

United States

The USEPA released their Reregistration Eligibility Decision for Endosulfan in November 2002.

The USEPA did not ban endosulfan but they did place stricter controls on the use of endosulfan formulations. The following table summarises the mitigation measures adopted by the USEPA.

Table H1: USEPA mitigation measures relevant to New Zealand: Summary of USEPA labelling changes for endosulfan.

Description	Labelling	Placement on Label	Existing HSNO equivalent control
Manufacturing-Use Products (MUP)			
Formulation instructions required for all MUP labels.	"Only for formulation into an *insecticide* for the following use(s)" *[fill blank only with those uses that are being supported by MP registrant*].	Directions for Use.	The substance endosulfan currently has a use restriction that it can only be used for research and development or as an ingredient in the manufacture of another substance or product. The substance endosulfan cannot be used as a pesticide or veterinary medicine but may be used in the formulation of a pesticide or veterinary medicine.
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use.	Currently no HSNO control. A control could be applied under s77A of the Act.
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Environmental Hazards" "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NDPES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your Water Board or Regional Office of the EPA." "This product is extremely toxic to fish and aquatic invertebrates and toxic to birds and mammals. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. See Spray drift management instructions under "Directions for use. Do not contaminate water when disposing of equipment wash waters or rinsate."	Precautionary Statements.	Identification and disposal controls apply.

Description	Labelling	Placement on Label	Existing HSNO equivalent control
End-Use Products Intended for Occupational Use			
Handler PPE Guidelines (all formulations)	Note the following information when preparing labelling for all end use products: For sole-active-ingredient end-use products that contain endosulfan, the product label must be revised to adopt the handler personal protective equipment (PPE)/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current label must be removed. PPE that will be established on the basis of Acute Toxicity testing on end-use products undergoing product reregistration must be compared with the active ingredient PPE specified below by the RED. The more protective PPE must be placed in the product labelling. For guidance on which PPE is considered more protective, see PR Notice 93- 7.	Handler PPE Statements.	Appropriate PPE required and identification requirements.
RUP Statement Required for All Formulations	"RESTRICTED USE PESTICIDE" "Due to acute toxicity to humans, aquatic organisms, and avian species." "For retail sale to and use only by certified applicators or persons under their direct supervision, and only for those uses covered by the certified applicator's certification.		Approved Handler requirement.
PPE Established by the RED for liquid formulations.	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" [*registrant inserts A,B,C,D,E,F,G, or H*] "on an EPA chemical-resistance category selection chart." "All handlers except those using engineering controls must wear: • Respirator with – an organic-vapour removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or – a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or	Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals.	Appropriate PPE required.

Description	Labelling	Placement on Label	Existing HSNO equivalent control
	– a NIOSH approved respirator with an (OV) cartridge or a canister with any N,R,P or HE filter. IN ADDITION: Mixers and loaders supporting aerial applications who are not using engineering controls (see engineering requirements below), handlers supporting or using high pressure handwand equipment and flaggers must wear: • Coveralls over long-sleeved shirt and long pants • Chemical resistant footwear plus socks • Chemical resistant gloves (except when flagging) • Chemical resistant head gear when exposed overhead • Chemical resistant apron when mixing and loading All other mixers, loaders applicators and handlers must wear: • Long-sleeved shirt and long pants; • Socks and shoes; • Chemical resistant gloves except, for applicators using enclosed cabs or cockpits, • Chemical resistant apron when mixing and loading, applying dips cleaning up spills or cleaning/repairing equipment. • A respirator of the type specified above for all handlers except for those using engineering controls."		
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Immediately following the PPE requirements.	Identification requirements apply.
Engineering Controls for Liquid Formulations	"Engineering Controls" "Mixers and loaders supporting aerial applications at the rate of more than 1.5 lbs/ai per acre or supporting applications to alfalfa, cotton, barley, rye oats and wheat must use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)] for dermal and	Precautionary Statements: Immediately following the User Safety Requirements.	Appropriate PPE required. No mandatory closed cab requirements. A means of compliance is given in the Code of Practice NZS 8409.

Description	Labelling	Placement on Label	Existing HSNO equivalent control
	inhalation protection, and must: • wear long-sleeved shirt, long pants, shoes, socks, chemical resistant gloves and chemical apron, • wear long-sleeved shirt, long pants, shoes, socks, and • be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown coveralls, chemical resistant footwear and the type of respirator specified in the PPE." "Applicators using airblast equipment on all crops except ornamental trees and shrubs must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, such applicators must: • wear the personal protective equipment required in the PPE section of this labelling, • *either* wear the type of respirator specified in the PPE section of this labelling *or* use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the type of respirator specified in the PPE section of this labelling, • be provided and must have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant footwear, chemical-resistant headgear, if overhead exposure, and, if using an enclosed cab that provides respiratory protection, a respirator of the type specified in the PPE section of this labelling, • take off any PPE that was worn in the treated area before re-entering the cab, and • store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab." "Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)];" "When handlers use closed systems and enclosed cabs, in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler		

Description	Labelling	Placement on Label	Existing HSNO equivalent control
	PPE requirements may be reduced or modified as specified in the WPS."		
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements: Immediately following Engineering Controls). Must be placed in a box.	Appropriate PPE required and identification requirements. A means of compliance is given in the Code of Practice NZS 8409.
Environmental Hazards	"Environmental Hazards" "This product is extremely toxic to fish and aquatic invertebrates and toxic to birds and mammals. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. See Spray drift management instructions under "Directions for use. Do not contaminate water when disposing of equipment wash waters or rinsate."	Precautionary Statements: Immediately following the User Safety Recommendations.	Into/ onto water control. No default control for drift other than Approved Handler. Spray drift management is covered in the Code of Practice NZS 8409.
Restricted Entry Interval (REI)	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI)."	Directions for Use in the Agricultural Use Requirements Box.	Currently no restricted entry intervals set.
Restricted Entry Intervals (REI) for EC Formulations	All crops except for the crops listed below have an REI of 48 hours. The following crop has an REI of 3 days: sweet potato. The following crops grown for seed have an REI of 3 days: collard greens, kale, mustard greens, radish, rutabaga, and turnip. The following crops NOT grown for seed have an REI of 4 days: kohlrabi, broccoli and cabbage. The following crops also have an REI of 4 days: brussel sprouts and cauliflower. The following crops have an REI of 6 days: blueberries.	Directions for Use next to the application instructions for each crop.	Currently no restricted entry intervals set.

Description	Labelling	Placement on Label	Existing HSNO equivalent control
	The following crops grown for seed have an REI of 7 days: kohlrabi, broccoli and cabbage The following crops have an REI of 17 days: sweet/fresh corn.		
Early Entry PPE	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: • coveralls, • chemical-resistant gloves made of any waterproof material, • shoes plus socks, • protective eyewear.	Directions for Use in the Agricultural Use Requirements Box.	Currently no specific HSNO control. The requirement for the use of PPE under both HSNO and HSE Acts would still apply.
Double Notification	"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated area."	Directions for Use in the Agricultural Use Requirements Box.	Currently no specific HSNO control. However, could be addressed by precautionary statements required to be on label.
Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Directions for Use.	Currently no specific HSNO control. However, the approved handler control, the use of NZS 8109, adherence to label statements would address this. There are also the requirements of the HSE and RMA which cover this. Could set a TEL.
Other Risk Mitigation	Reduced Application Rates (maximum a.i. per acre or per gallon per application) Tree bark application: 0.005 lb/ai gallon Broccoli, kohlrabi, cabbage and cauliflower not grown not for seed: 1.0 lb ai/acre Strawberries: 1.0 lb ai/acre Cotton (ground applications) and blueberries: 1.5 lb ai/acre Pome fruit, stone fruit, nonbearing citrus, pecans and ornamental trees and shrubs: 2.5 lb ai/acre. Reduce Seasonal Application Rate (maximum amount a.i./acre that can be applied in a single season) Sweet/fresh corn, cotton (aerial application) and blueberries: Reduce to 1.5 lbs ai/acre per season	Directions for Use under application instructions and/or restrictions.	Currently no application rates set. A control could be applied under s77A of the Act or set an EELs which require setting of application rates.

Description	Labelling	Placement on Label	Existing HSNO equivalent control
	Melons, cucumbers, squash, pumpkins, lettuce, tomatoes, sweet potato, cotton (ground applications), broccoli, cauliflower, cabbage, kohlrabi, brussel sprouts, strawberries, filberts, walnuts, almonds, macadamia nuts, peppers, egg plant, potatoes, carrots, dried beans, dried peas and tobacco: Reduce to 2.0 lbs ai/acre per season. Pome fruit, stone fruit, nonbearing citrus and pecans: Reduce to 2.5 lbs ai/acre per season. Reduce Number of Applications/Season (max. # of applications that can be made in one season) Broccoli, brussels sprouts, cauliflower, cabbage, cotton, dry deans, dry peas, kohlrabi, lettuce, strawberry, sweet potatoes, tobacco: Reduce to 2 applications per season. Melons, cucumber, squash and pumpkins: Reduce to 4 applications per season except for CA where the maximum number of applications per season is 3. Potatoes, tomatoes: Reduce to 4 applications per season. Application Equipment/Method Deletions: For all formulations, prohibit use of high pressure hand wand on all sites except to bark treatment or tobacco drench.		
Spray Drift Labelling	"Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, non-target crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals." "A 30 ft. vegetative buffer strip must be maintained between all areas treated with this product and rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries and commercial fish ponds." "For ground boom applications, do not apply within 100 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries and commercial fish ponds. Apply with nozzle height no more than 4 feet above the ground or crop canopy and when wind speed is 10 mph or less at the application site as measured by an anemometer. Use (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomiser nozzles."	Directions for Use under General application instructions and/or restrictions.	Currently no buffer zones applied. Approved handler requirements apply. Good agricultural practice expected from approved handler to control spray drift. A buffer zone control could be applied under s77Aof the Act. There are also the requirements of the RMA which cover this.

Description	Labelling	Placement on Label	Existing HSNO equivalent control
	"For orchard/vineyard airblast applications, do not apply within 100 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries and commercial fish ponds. Direct spray above trees/vines and turn off outward pointing nozzles at row ends and outer rows. Apply only when wind speed is 3 –10 mph at the application site as measured by an anemometer outside of the orchard/vineyard on the upwind side." "For aerial applications, do not apply within 300 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries and commercial fish ponds. The boom width must not exceed 75% of the wingspan or 90% of the rotary blade. Use upwind swath displacement and apply only when wind speed is 3 -- 10 mph as measured by an anemometer. Use _____ (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomiser nozzles. If application includes a nospray zone, do not release spray at a height greater than 10 feet above the ground or the crop canopy." "For overhead chemigation, do not apply within 100 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries and commercial fish ponds. Apply only when wind speed is 10 mph or less." "The applicator also must use all other measures necessary to control drift."		

Table H2: USEPA mitigation measures relevant to New Zealand: dietary, ecological and occupational risks

Dietary (Drinking Water) and Ecological Risk: Several mitigation measures are needed to reduce the potential for contamination of drinking water.	
• Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A for melons, cucurbits, lettuce, tomatoes, sweet potatoes, cotton (ground), broccoli, cauliflower, cabbage, kohlrabi, brussels sprouts, strawberries, filberts, walnuts, almonds, macadamia nuts, peppers, eggplant, potatoes, carrots, dry beans, dry peas, and tobacco.	**HSNO equivalent:** Currently no application rates set for endosulfan formulations
• Reduce maximum seasonal application rate from 3 lbs./ai/A to 1.5 lbs./ai/A for sweet corn, cotton (aerial) and blueberries.	**HSNO equivalent:** Currently no application rates set for endosulfan formulations
• Require 100 ft. spray buffer for ground applications between a treated area and water bodies.	**HSNO equivalent:** Into/ onto water control applies to endosulfan formulations. Currently no buffer zones applied for endosulfan formulations.
• Require 30 ft. maintained vegetative buffer strip between a treated area and water bodies.	**HSNO equivalent:** Currently no vegetative buffer strips applied for endosulfan formulations.
• Require all products to be Restricted Use.	**HSNO equivalent:** Users of endosulfan formulations required to be Approved Handlers
Occupational Risk	
• Require closed mixing/loading systems for aerial application using the EC formulation on pome fruits, stone fruits, citrus, sweet corn, sweet potatoes, cotton, collard greens (seed), kale (seed), mustard greens (seed), radish (seed), turnip (seed), rutabaga (seed), broccoli, (seed), cauliflower (seed), kohlrabi (seed), cabbage (seed), blueberries, small grains, alfalfa (seed), filberts, walnuts, almonds and macadamia nuts.	**HSNO equivalent:** Currently no requirement for closed mixing/loading systems for endosulfan formulations.
• Require closed cabs for airblast applications on pome fruits, stone fruits, citrus, filberts, walnuts, almonds and macadamia nuts.	**HSNO equivalent:** Currently no requirement for closed cabs for endosulfan formulations.
• Prohibit use of high pressure handwands with rates greater than 0.005 lbs/ai/gal.	**HSNO equivalent:** Currently no restrictions on handwands for endosulfan formulations.
• Increase REI to 48 hours for all crops except as noted in the following bullets; • Increase REI for EC products to 4 days for broccoli, cauliflower, kohlrabi, cabbage, and brussels sprouts; • Increase REI for EC products to 6 days for blueberries; • Increase REI for EC products to 7 days for broccoli (seed), kohlrabi (seed), and cabbage (seed); and • Increase REI for EC products to 17 days for sweet corn.	**HSNO equivalent:** Currently no re entry intervals set for endosulfan formulations.

Canada

Canada is currently in the process of reassessing endosulfan. As part of the review they have proposed a number of mitigation measures.

The following section summarises the mitigation measures being assessed by Canada and the preliminary risk assessment as to the possible effectiveness of the measures.

Canada's Pest Management Regulatory Agency (PMRA) is proposing to implement the following measures, as a precautionary approach to reduce occupational and environmental exposure to endosulfan. Preliminary assessment of these mitigation measures was published October 2007. Where assessed the feasibility report is given.

Table H3: PMRA Mitigation Measures Relevant to New Zealand: Proposed measures pertaining to occupational and environmental risks

Application Rates and Re-Entry Intervals	
• Use a maximum rate of 0.6 g a.i./L when endosulfan is applied with high pressure handwand equipment.	**Existing HSNO equivalent control:** Currently no application rates set under HSNO.
Establish the following re-entry intervals (REIs) for workers entering treated areas: • 16 days for Brussels sprouts, broccoli, cabbages and cauliflower; Feasibility: unlikely • 10 days for sweet corn; and Feasibility: unknown • 48 hours for all other crops.	**Existing HSNO equivalent control:** Currently no HSNO control. A re-entry control could be applied under s77A of the Act.
The maximum rate per application must not exceed: • 2.8 kg a.i./ha for pome fruit, stone fruit, ornamental trees and shrubs; Feasibility: unknown • 1.1 kg a.i./ha for strawberries. Feasibility: likely The maximum seasonal application rate must not exceed: • 1.7 kg a.i./ha for corn; Feasibility: unknown • 2.2 kg a.i./ha for melon, cucumber, squash, pumpkin, tomatoes, pepper, eggplant, potatoes, beans, peas and strawberries; Feasibility: likely • 2.8 kg a.i./ha for apples, pears, apricots, peaches, plums and cherries; and 1.1 kg a.i./ha for celery. The maximum number of applications per season must not exceed: • 4 for melons, cucumbers, squashes, pumpkins, potatoes and tomatoes; • 2 for broccoli, Brussels sprouts, cauliflower, cabbages, beans, peas, lettuce, eggplants, peppers and strawberries; and • 1 for corn.	**Existing HSNO equivalent control:** Currently no application rates set under HSNO.
Personal Protective Equipment (PPE): The following personal protective equipment (PPE) is to be used to reduce exposure to workers.	
Workers using high-pressure handwand equipment: • Wear coveralls over a long shirt and long pants, chemical-resistant footwear, chemical-resistant gloves and an approved organic vapour respirator during application. In addition to this protective equipment, wear a chemical-resistant apron during mixing/loading, clean-up, repair and all other handling activities.	**Existing HSNO equivalent control:** Appropriate PPE required.

Applicators using airblast equipment on pome and stone fruit crops: • Applicators using airblast equipment on pome and stone fruit crops must use enclosed cabs and wear a long-sleeved shirt, long pants shoes plus socks and either an approved organic vapour respirator or an enclosed cab that provides as much respiratory protection as an organic vapour respirator. When exiting the cab in the treated area, applicator must wear coveralls, chemical-resistant footwear, chemical-resistant headgear and an approved organic vapour respirator. Those PPE must be taken off before re-entering the cab and stored in a chemical-resistant container to prevent contamination of the inside of the cab.	**Existing HSNO equivalent control:** Appropriate PPE required. A control specifying a closed cab could be applied under s77A of the HSNO Act.
Early entry to treated areas: • If early entry into treated areas is required (i.e., prior to the specified REI), workers must wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, shoes plus socks and goggles or a face shield. **All other workers:** • Wear a long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves and an approved organic vapour respirator during mixing/loading, clean-up, repair, application and all other handling activities. In addition to this protective equipment, wear a chemical-resistant apron during mixing/loading, application of dips, clean-up and repair activities.	**Existing HSNO equivalent control:** Currently no equivalent specific HSNO control. There is a general requirement for PPE (also under HSE Act) and label warning.
To Mitigate Contamination of Aquatic Environments	
• Require a 10 metre vegetative buffer strip be maintained between all areas treated with endosulfan and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), and estuarine/marine habitats. • Require a 30 metre buffer zone between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), and estuarine/marine habitats.	**Existing HSNO equivalent control:** Currently no equivalent specific HSNO control. A buffer zone control could be applied under s77A of the Act or EELs could be set.
• [Note: endosulfan products are currently restricted to application with ground equipment].	**Existing HSNO equivalent control:** Currently no HSNO control. An application method control could be applied under s77A of the Act.
Removal of Unsupported Uses: Certain uses for endosulfan were unsupported by registrants in the U.S. and cancelled in that country prior to publication of the USEPA RED document. The registrants of technical grade endosulfan for Canada (Bayer CropScience Inc. and Makhteshim-Agan of North America Inc.) have withdrawn support for the following similar uses in Canada:	
• Greenhouse ornamentals • Residential uses These uses of endosulfan will be phased out.	**Existing HSNO equivalent control:** Currently no HSNO control. A control restricting uses could be applied under s77A of the Act. The approved handler and tracking controls effectively rule out residential use.

Australia

In Australia the APVMA released their Final Review Document on Endosulfan in 2005.

Australia did not ban endosulfan but they did place stricter controls on the use of endosulfan formulations. The following section summarises the mitigation measures adopted by Australia.

Australian Mitigation Measures Relevant to New Zealand

Endosulfan MUST NO LONGER be used:

- on leafy vegetables, berry fruits (including grapes), bananas, sorghum & maize, peanuts, legume vegetables, bulb vegetables, sweet corn, or cole vegetables [except cabbage (head) broccoli and cauliflower];
- for post-emergent uses on cereals, pulses and oil seeds (except cotton);
- on any pasture, forage and fodder species including clover, lucerne, chou moellier, medic crops and vetch.

The following table compares the current New Zealand registered uses and the outcome of the APVMA review.

Table H4: Current New Zealand registered uses and the APVMA review

Crop with current New Zealand registration	Australian Review Outcome
Tomatoes	Retain
Potatoes	Delete (Trade risk)
Onions	Delete (No data)
Cabbage, cauliflower and other vegetable brassicas	Retain for broccoli, cabbage (head) and cauliflower deleted for other cole vegetables
Fodder crop seedlings	Delete
Maize and sweetcorn	Delete (Trade risk)
Strawberries	Delete (No data)
Blackberries, boysenberries, raspberries	Delete (No data)
Gooseberries, blackcurrants	Delete (No data)
Ornamentals	Retain

Table H5: APVMA review, deleted non-crop uses relevant to New Zealand

Lawn/turf	**Existing HSNO equivalent controls**: There is currently no restriction on the use of endosulfan products on turf.
Endosulfan products are not registered for home garden use in Australia.	**Existing HSNO equivalent controls**: There is currently no restriction on endosulfan products for home garden use Although the approved handler control effectively rules this out.

Table H6: APVMA review, safety directions: the following amended safety instructions have been included on labels:

• RE-ENTRY PERIODS: The following re-entry period has been added to endosulfan product labels. Re-entry: Do not allow re-entry into treated areas until the spray has dried.	**Existing HSNO equivalent controls:** There is currently no HSNO control applying a re-entry period.
• Very dangerous, particularly the concentrate product. Undiluted product poisonous if absorbed by skin contact, inhaled or swallowed. Will damage eyes. Will irritate the nose and throat and skin. Avoid contact with eyes and skin. Do not inhale vapour. If clothing becomes contaminated with product or wet with spray remove clothing immediately. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. • When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist [or equivalent clothing], elbow-length PVC gloves, and a full facepiece (or half facepiece and goggles) respirator. • When using the prepared spray, wear cotton overalls buttoned to the neck and wrist [or equivalent clothing]. • After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, respirator (and if rubber wash with detergent and warm water), goggles and contaminated clothing	**Existing HSNO equivalent controls**: Appropriate PPE controls and precautionary labelling requirements apply to endosulfan products. These are not as specific as the Australian instructions.
• <u>Precautionary statement:</u> For aerial application, support workers/markers should be protected by enclosed cabs.	**Existing HSNO equivalent controls**: There is currently no HSNO control specifying a requirement for closed cabs. Precautionary statements on how to avoid exposure are required on labels.
• All supply and use of endosulfan products must be as directed on currently approved product labels.	**Existing HSNO equivalent controls**: There are currently no use restrictions specified for the HSNO approvals of endosulfan products. Use restrictions apply to areas of use covered by ACVM but this does not cover home garden or turf use.
Endosulfan products must only be purchased and used by Authorised Persons. For the purposes of s.94 of the Agvet Codes, the APVMA advises that an "Authorised Person" is one who: • conducts the business of selling or supplying agricultural chemical products; • or are current State licensed pesticide applicators; • or hold a current Spray Safe Certificate for successful completion of the Chemical Handling Manual for Agricultural Aviation under Operation Spray Safe issued by the Aerial Agricultural Association of Australia (AAAA); or • hold a current Certificate (AQF level 3 or above) or statement of attainment issued by a Registered Training Organisation for the following two competency units: • RTC3705A Transport, handle and store chemicals • RTC3704A Prepare and apply chemicals.	**Existing HSNO equivalent controls**: Approved handler control applied to all endosulfan products.

The following limits on the number of applications of endosulfan must be observed: • for all crops except orchard crops, the limit is two full coverage sprays of endosulfan per crop per growth season unless irrigation and storm runoff water (25 mm) is captured on farm.	**Existing HSNO equivalent controls**: Currently no application rates or limits on number of applications set under HSNO for endosulfan products..
• Users of endosulfan products must keep records according to instructions found on the new approved label. These records must be kept for two years.	**Existing HSNO equivalent controls**: HSNO tracking control currently applies to all endosulfan products.
The following livestock feeding restraints have been included on all product labels where appropriate: • Do not feed treated tomato crops to livestock.	**Existing HSNO equivalent controls**: Controls of this nature set by ACVM.

Appendix I – Potential alternatives to endosulfan

Alternatives to endosulfan for crop pest control

Alternative insecticide products currently registered for the crop/pest combinations for which endosulfan is registered (Section 6) include, but are not necessarily limited to, those shown in Table I1. This information was sourced from the New Zealand Agrichemical Manual 2007 with uses confirmed on the ACVM database of currently registered Veterinary Medicines, Plant Compounds and Vertebrate Toxic Agents.

Table I1: Alternative insecticide products

CROP	PEST	Currently Registered Alternatives
Tomatoes	Aphids	**Organophosphates** bifenthrin – *Talstar 80 SC, Venom, Talstar 100 EC* diazinon – *Diazinon 50W, DEW 500, Diazinon 800, Jolyn DIGRUB, Diazol* maldison – *Malathion 50EC* **Synthetic pyrethroids** alpha-cypermethrin – *Zenith, Dominex 100, Alpha*-Scud, Fastac **Carbamates** pirimicarb – *Pirimor 50, Prohive , Pirimisect , Pirimax 500, Aphidex WG Insecticide* **Pyridine azomethine** pymetrozine – *Chess WG* **Other** *pyrethrum – Key Pyrethrum*
	Thrips	**Organophosphates** diazinon – *Diazinon 50W, DEW 500, Diazinon 800, Jolyn DIGRUB , Diazonyl 60EC , Diazol*
	Green vegetable bug	**Organophosphates** trichlorfon – *Trifon*
	Whitefly	**Pyridine azomethine** pymetrozine – *Chess WG*

CROP	PEST	Currently Registered Alternatives
	Cutworms	**Organophosphates** chlorpyrifos **–** *Lorsban 50EC* trichlorfon – *Trifon* **Synthetic pyrethroids** lambda-cthalothrin – *Karate Zeon* esfenvalerate – *Sumi-Alpha* **Macrocyclic lactone** spinosad – *SUCCESS *NATURALYTE* INSECT CONTROL , Entrust Naturalyte Insect Control*
	other caterpillars	**Organophosphates** methamidaphos – *Tamaron, Methafos 600* diazinon – *Diazinon 50W, DEW 500, Diazinon 800, Jolyn DIGRUB, Diazol* malathion 50EC – *maldison* acephate – *Orthene , Lancer 750 DF* **Carbamates** carbaryl – *Carbaryl 50F, Sevin Flo*
Potatoes (both table and seed potatoes)	Potato tuber moth	**Organophosphates** methamidaphos – *Tamaron, Methafos 600* acephate – *Orthene , Lancer 750 DF* phorate, – *Nufarm Phorate, Crop Care Phorate 20G, Disect, Thimet 20G* **Synthetic pyrethroids** deltamethrin – *Ballistic, Decis Forte, Deltaphar 25EC* lambda-cyhalothrin – *Karate Zeon*

CROP	PEST	Currently Registered Alternatives
		Carbamates carbaryl – *Carbaryl 50F, Sevin Flo* **Macrocyclic lactone** spinosad – *SUCCESS *NATURALYTE* INSECT CONTROL, Entrust Naturalyte Insect Control*
	Aphids	**Organophosphates** methamidaphos – *Tamaron, Methafos 600* pirimicarb – *Pirimor 50, Prohive, Pirimisect, Pirimax 500, Aphidex WG Insecticide* acephate – *Orthene, Lancer 750 DF Dimethoate – ROGOR E, PERFEKTHION S, DIMEZYL 40EC* **Chloronicotinyl** imidacloprid – *Gaucho* **Pyridine azomethine** pymetrozine – *Chess WG* **Other** *pyrethrum – Key Pyrethrum*
	Green looper caterpillar	**Carbamates** carbaryl – Carbaryl 50F, Sevin Flo
Onions (except spring onions)	Onion thrips	**Organophosphates** methamidaphos – *Tamaron, Methafos 600* chlorpyrifos – *Toppel, Pyrinex* dichlorvos – *Nuvos* diazinon – *Diazinon 50W, DEW 500, Diazinon 800, Jolyn DIGRUB, Diazonyl 60E, Diazol*

CROP	PEST	Currently Registered Alternatives
		Synthetic pyrethroids deltamethrin – *Ballistic, Decis Forte, Deltaphar 25EC* lambda-cyhalothrin – *Karate Zeon* alpha-cypermethrim – *Alpha-Scud, Bestseller 100EC, Fastac, Dominex 100, Cypher* tau-fluvalinate – *Mavrik Aquaflo, Mavrik flo* esfenvalerate – *Sumi-Alpha* **Chloronicotinyl** imidacloprid – *Confidor, Pilarking 200SL* **Mixed actives** imidacloprid and cyfluthrin – *Confidor Supra*
Cabbage, cauliflower and other vegetable brassicas	Aphids	**Chloronicotinyl** imidacloprid – *Confidor* thiacloprid – *Calypso* **Organophosphates** methamidaphos – *Tamaron, Methafos 600* chlorpyrifos – *Toppel, Pyrinex* dichlorvos – *Nuvos, Divap* diazinon – *Diazinon 50W, DEW 500, Diazinon 800, Diazonyl 60E, Diazol* chlorpyrifos – *Lorsban 50EC, Chlorpyrifos 48EC* maldison – Malathion 50EC phorate, – *Nufarm Phorate, Crop Care Phorate 20G , Disect, Thimet 20G* **Carbamates** pirimicarb – *Pirimor 50, Prohive , Pirimisect , Pirimax 500, Aphidex WG Insecticide*

CROP	PEST	Currently Registered Alternatives
		Pyridine azomethine pymetrozine – *Chess WG* **Biological** bacillus thuringiensis – *Agree WDG* **Other** *pyrethrum – Key Pyrethrum*
	Diamond-back moth	**Organophosphates** methamidaphos – *Tamaron, Methafos 600* acephate – *Orthene, Lancer 750 DF* maldison – *Malathion 50EC* trichlorfon – *Trifon* **Synthetic pyrethroids** alpha-cypermethrim – *Alpha-Scud , Fastac , Dominex 100* deltamethrin – *Ballistic, Decis Forte, Deltaphar 25EC* lambda-cyhalothrin – *Karate Zeon* tau-fluvalinate – *Mavrik flo* cypermethrin – *Ripcord* esfenvalerate – *Sumi-Alpha* bifenthrin – *Talstar 80 SC, Venom* **Macrocyclic lactone** spinosad – *Success Naturalyte Insect Control, Entrust Naturalyte Insect Control* **Phenyl pyrazole** fipronil – *Ascend*

CROP	PEST	Currently Registered Alternatives
		Biological Bacillus thuringiensis – *Agree WDG, Xen Tari WDG , Delfin WDG* **Mixed Actives** trichlorfon and cypermethrin – *Partna* **Oxadiazine** indoxacarb – *Steward 150 SC*
	White butterfly caterpillars	**Organophosphates** methamidaphos – *Methafos 600* dichlorvos - *Nuvos* diazinon - *Diazinon 50W, DEW 500 , Diazinon 800, Diazonyl 60EC, , Diazol* acephate - *Orthene , Lancer 750 DF* maldison - *Malathion 50EC* trichlorfon - *Trifon* **Synthetic pyrethroids** alpha-cypermethrim - *Alpha-Scud , Bestseller100EC, Fastac , Dominex 100, Zenith* deltamethrin – *Ballistic, Decis Forte, Deltaphar 25EC* lambda-cyhalothrin - *Karate Zeon* mavrik flo – *tau-fluvalinate* cypermethrin - *Ripcord* esfenvalerate - *Sumi-Alpha* bifenthrin - *Talstar 80 SC, Venom* **Mixed actives** partna – trichlorfon and cypermethrin

CROP	PEST	Currently Registered Alternatives
		Carbamates carbaryl - *Carbaryl 50F, Sevin Flo* **Macrocyclic lactone** spinosad – Success Naturalyte Insect Control, Entrust Naturalyte Insect Control Phenyl pyrazole fipronil - *Ascend* **Oxadiazine** indoxacarb - *Steward 150 SC* **Biological** bacillus thuringiensis - *Agree WDG , Xen Tari WDG, Delfin WDG*
Fodder crop seedlings (turnips, swedes, choumoellier, feed rape, fodder-beet, mangolds) Also **brassica vegetable seedlings**	Nysius bug *(Nysius huttoni)*	**Organophosphates** chlorpyrifos - *Lorsban 50EC* fenitrothion - *Caterkil 1000* terfufos - *Counter* phorate, - *Nufarm Phorate, Crop Care Phorate 20G , Disect, Thimet 20G* **Chloronicotinyl** imidacloprid - *Gaucho*
Maize and sweetcorn (seedlings)	Cutworm	**Organophosphates** chlorpyrifos - *Lorsban 50EC* ,Pyrinex , Toppel **Synthetic pyrethroids** alpha-cypermethrim - *Alpha-Scud, Bestseller 100EC, Fastac , Dominex 100* deltamethrin - *Ballistic , Decis Forte , Deltaphar 25EC* lambda-cyhalothrin - *Karate Zeon*

CROP	PEST	Currently Registered Alternatives
		alpha-cypermethrin - *Cypher* esfenvalerate - *Sumi-Alpha* **Carbamates** carbaryl - *Carbaryl 50F, Sevin Flo* methomyl - *Lannate L*
Strawberries	Aphids	**Organophosphates** dichlorvos – *Nuvos* diazinon - *DEW 500, Diazol* dimethoate - Dimexyl 40 EC, Perfekthion S phorate, - *Nufarm Phorate, Crop Care Phorate 20G , Disect, Thimet 20G* **Carbamate** methomyl - *Lannate L* **Biological** aphidoletes aphidimyza- Aphidoletes **Chlorinated hydrocarbon** dicofol - *Kelthane 35* **Other** *pyrethrum – Key Pyrethrum*
	Cyclamen (strawberry) mite	**Organophosphates** dichlorvos – *Nuvos*

CROP	PEST	Currently Registered Alternatives
Blackberries, Boysenberries, Raspberries, Gooseberries, Blackcurrants	Aphids	**Organophosphates** dichlorvos – *Nuvos, Divap* dimethoate - Rogor E, Perfekthion S **Other** *pyrethrum – Key Pyrethrum*
	Bronze beetle	
	Redberry mite	**Organophosphates** dichlorvos – *Nuvos, Divap*
Ornamentals (glasshouse and out of doors)	Cyclamen mite	**Organophosphates** dichlorvos – *Nuvos, Divap* phorate, - *Nufarm Phorate, Crop Care Phorate 20G , Disect, Thimet 20G*
	Aphids	**Organophosphates** dichlorvos – *Nuvos, Divap* phorate, - *Nufarm Phorate, Crop Care Phorate 20G , Disect, Thimet 20G* diazinon - Diazinon 50W acephate - Orthene , Lancer 750 DF chlorpyriphos – *chlorpyriphos WP* maldison - *Malathion 50EC* **Synthetic pyrethroids** tau-fluvalinate - *Mavrik Aquaflo, Nursery Maverik* bifenthrin – *Talstar 80 SC*

CROP	PEST	Currently Registered Alternatives
		Biological Aphidius colemani – *Aphidus , Aphipar* Aphidoletes aphidimyza – *Aphidoletes* **Chloronicotinyl** imidacloprid – *Confidor* **Other** azadirachtin – *Neemazal – T/S* *pyrethrum – Key Pyrethrum*

Alternatives to endosulfan for earthworm control on turf

A number of pesticides have been identified as having the potential to kill earthworms 9see http://www.oxfordcroquet.com/care/worms/index.asp). However, their efficacy and effectiveness in a field situation in New Zealand are presently unknown. The main alternatives are summarised in Table I2.

Table I2: Pesticides for treatment of earthworms in turf

Potential pesticide options presently available within New Zealand for controlling earthworms			
Product	**Rate/ha**	**Product cost $/ha**	**Comments**
Endosulfan 350gai/L Acute oral LD_{50} 80–110mg/kg rats Acute dermal LD_{50} 359mg/kg rabbits	2L	60	• Field experience has shown endosulfan to provide the most reliable and effective control of earthworms. • A single application per year is typically adequate to reduce casting by approximately 90–95%
Carbaryl 500gai/L Acute oral LD_{50} 400mg/kg rats Acute dermalLD_{50} 500mg/kg rats	10–30L	209–627	• On ERMA New Zealand's Chief Executive Priority List for Reassessment. • Although there has been limited field use of carbaryl (given availability of endosulfan) field experience has shown it to provide inconsistent or partial control of earthworms. • Research$_3$ has shown carbaryl to be less effective and provide a shorter duration of control than carbendazim.
Carbendazim 500gai/L Acute oral LD_{50} 6400mg/kg rats Acute dermal LD_{50} >10000mg/kg rabbits	4–8L	112–224	• On ERMA New Zealand's Chief Executive Priority List for Reassessment. • Product labels overseas (eg Scotts Turfclear) require this to be applied every 3 months • Research indicates that carbendazim, will suppress the amount of casting that occurs by approximately 35% for 3months and thereafter the level of control will taper off with time. **Except in minor outbreaks this level of casting suppression would be inadequate to achieve the desired level of improvement.** • Resistance to benzimidazole group of fungicides and in particular Benlate™ to Dollar spot and Fusarium is well documented on New Zealand turf facilities. Furthermore cross resistance within the benzimidazole group of fungicides is well documented. • Repeated drenches of carbendazim increase the risk of resistance to a range of fungi occurring.

Appendix J – Parties contacted

Central Government	
New Zealand Food Safety Authority	Department of Labour
Ministry of Health	
Local Government: North Island	
Auckland City Council	Otorohanga Regional Council
Auckland Regional Council	Palmerston North City Council
Carterton District Council	Papakura District Council
Central Hawkes Bay District Council	Porirua City Council
Environment Bay of Plenty	Rangitikei District Council
Environment Waikato	Rodney District Council
Far North District Council	Rotorua District Council
Franklin District Council	Ruapehu District Council
Gisborne District Council	South Taranaki District Council
Greater Wellington Regional Council	South Waikato District Council
Hamilton City Council	South Wairarapa District Council
Hastings District Council	Stratford District Council
Hauraki District Council	Taranaki Regional Council
Hawkes Bay Regional Council	Tararua District Council
Horizons Regional Council	Taupo District Council
Horowhenua District Council	Tauranga City Council
Hutt City Council	Thames–Coromandel District Council
Kaipara District Council	Upper Hutt City Council
Kapiti Coast District Council	Waikato District Council
Kawerau District Council	Waipa District Council
Manawatu District Council	Wairoa District Council
Manukau City Council	Waitakere City Council
Masterton District Council	Waitomo District Council
Matamata–Piako District Council	Wanganui District Council
Napier City Council	Wellington City Council
New Plymouth District Council	Western Bay of Plenty District Council
North Shore City Council	Whakatane District Council

Northland Regional Council Opotiki District Council	Whangarei District Council
Local Government: South Island	
Ashburton District Council Buller District Council Central Otago District Council Chatham Islands Council Christchurch City Council Clutha District Council Dunedin City Council Environment Canterbury Environment Southland Gore District Council Grey District Council Hurunui District Council Invercargill City Council Kaikoura District Council	Mackenzie District Council Marlborough District Council Nelson City Council Otago Regional Council Queenstown Lakes District Council Selwyn District Council Southland District Council Tasman District Council Timaru District Council Waimakariri District Council Waimate District Council Waitaki District Council West Coast Regional Council Westland District Council
CEIR Submitters who referred to endosulfan	
Breast Cancer Network NZ Inc (Barbara Mason, Gillian Woods) NZ Sports Turf Institute (Brian Way) Pesticide Action Network Aotearoa New Zealand (Meriel Watts) Soil and Health Association of New Zealand (Steffan Browning) Safe Food Campaign (Alison White)	
Turf	
Evans Turf Supplies (Tony Evans)	PGG Wrightson Turf (Bill Walmsley)
Aviation	
New Zealand Agricultural Aviation Association Civil Aviation Authority of New Zealand	Auckland Airport

Registrants	
Bayer NZ Ltd Adria NZ Ltd	Agronica NZ Ltd (Makhteshim)
Others	
National Poison Centre	
Horticulture NZ New Zealand Association for Animal Health and Crop Protection (AGCARM) Spraywatch The International Stewardship Centre for Endosulfan (Sherman Friedman) SPCA Auckland (Bob Kerridge)	New Zealand Chemical Industry Council Federated Farmers

Appendix K – Confidential appendix – Report of M Edwards on Davies (2002) dermal absorption study

Appendix L – Confidential appendix – Product formulations