# ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

10 December 2008

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|---|---|
| Application Code | HRC07003 |
| Application Type | To reassess a hazardous substance under section 63 of the Hazardous Substances and New Organisms Act 1996 ("the Act") |
| Applicant | Chief Executive of ERMA New Zealand ("the Chief Executive") |
| Application Received | 27 June 2008 |
| Submission Period | 27 June – 8 August 2008 |
| Hearing dates | 21-22 October 2008 |
| Considered by | A Committee of the Authority ("the Committee") |
| Purpose of the Application | An application for the reassessment of endosulfan and formulations containing endosulfan under section 63 of the Act. |

## 1 Summary of decision

1.1 The Committee:

(a) declines to approve the further importation or manufacture of endosulfan and formulations containing endosulfan and accordingly revokes the following approvals:

- endosulfan (Approval Number HSR002846);
- emulsifiable concentrate containing 350 g/litre endosulfan (Substance A) (Approval Number HSR000679);
- emulsifiable concentrate containing 350 g/litre endosulfan (Substance B) (Approval Number HSR000678);
- emulsifiable concentrate containing 350 g/litre endosulfan (Substance C) (Approval Number HSR000487);
- emulsifiable concentrate containing 350 g/litre endosulfan (Substance D) (Approval Number HSR000677),

(b) in accordance with section 66 of the Act issues a direction to prohibit the use of endosulfan or any of the above formulations for any purpose, and imposes controls on the disposal of all stocks of endosulfan.

This decision will come into effect 28 days after publication of the direction in the gazette.

1.2 The Committee considers that the decision should be implemented as soon as possible. However, the Committee also recognises that the decision must be communicated

before it has effect. For this reason the Committee has directed that the decision should come into effect 28 days after the direction is published in the *Gazette*.

# 2 Background

2.1 This decision should be read in conjunction with the Agency's reassessment application dated 27 June 2008 and the subsequent Update Paper provided to the Committee prior to the hearing, which summarised the submissions and new information received following notification of the application.

2.2 For the purposes of this reassessment, it is noted that only emulsifiable concentrate formulations containing 350 g/l endosulfan are approved and available in New Zealand.

2.3 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, earthworm control on turf at golf courses, bowling clubs, parks, sports grounds, and at airports.

2.4 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 resulting from the availability of some new insecticide chemistry.

2.5 Four products using endosulfan are currently approved for use in New Zealand, but only one of the three companies provided information to support the continued use of endosulfan in New Zealand. Two companies did not want to support continued use and the fourth indicated that they were only interested in importing for use in the coming season.

2.6 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.

2.7 The Agency understands that no endosulfan formulations are marketed for domestic use in New Zealand and that aerial application does not take place in New Zealand. These potential uses were therefore not evaluated.

2.8 Horticulture New Zealand has estimated the total endosulfan market in New Zealand to be in the vicinity of 15,000 to 20,000 litres per year (approximate figure for 2007 estimated from discussion with P. Ensor, Horticulture New Zealand pers. comm.). However since 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.

[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.

# 3 Application process

3.1 The application was publicly notified on 27 June 2008 (on ERMA New Zealand's web site) and was advertised in the four main newspapers (New Zealand Herald, Dominion Post, Christchurch Press and Otago Daily Times).

3.2 Submissions closed on 8 August 2008, 30 working days after public notification.

3.3 Various Government departments, Crown Entities and interested parties, including the New Zealand Food Safety Authority (Agricultural Compounds and Veterinary Medicines (ACVM) Group), the Ministry of Health and the Department of Labour Work Place Group, which in the opinion of the Authority would be likely to have an interest in the application, were notified of the receipt of the application and provided with an opportunity to comment or make a submission on the application.

3.4 The Agency received 187 submissions on this application.

3.5 In accordance with section 60 and clause 2(b), a public hearing was held 21-22 October 2008 at the Mercure Hotel, 355 Willis Street, Wellington.

3.6 An Update Paper to the application was prepared by the Agency and provided to the decision making Committee on 7th October 2008. This paper included:

- A summary of new information received;
- Responses from submitters to questions raised in the application;
- Summary of additional environmental (aquatic) modelling;
- The Agency's responses to issues raised in the submissions;
- Ngā Kaihautū Tikanga Taiao report on the application;
- NZ Sports Turf Institute submission outlining results of a survey of Councils on the acceptability of the proposed controls;
- Conclusions by the Agency.

3.7 The following members of the Authority's Hearings Committee considered the application: Helen Atkins (Chair), Richard Woods and Dr Deborah Read.

3.8 The following external experts were used in the consideration of this application:

| Name | Title |
|---|---|
| Robin Toy | Ecotoxicologist |
| Dr Martin Edwards | Toxicologist |

3.9 The Agency's project team comprised the following members of ERMA New Zealand staff:

| Name | Title |
|---|---|
| Dr Susan Collier | Senior Advisor Hazardous Substances |
| Jim Waters | Senior Advisor Hazardous Substances |
| Paul Downie | Administration Assistant |
| Janet Gough | Principal Analyst |
| Michael Morris | Manager, Reassessments |

# 4 The public hearing

4.1 The names of those who made oral presentations at the hearing are given in **Appendix 2**.

4.2 The Committee heard from the Agency as applicant. The Agency provided a summary of the application and a written response to the matters raised in submissions.

4.3 The Committee then heard from all those submitters who had requested to be heard over the two days of its hearing. The majority of submitters (Elizabeth Harris, Mike Eccles, David McBride, Alison Roe, Donna Bird of Many Affected Friends of Aotearoa (MAFIA), Peter Revington of Meat and Wool New Zealand, Catherine Delahunty, Sue Kedgley of Green Party of Aotearoa New Zealand, Alison White of Safe Food Campaign, Alison White on behalf of Jacqui Knight of Monarch Butterfly New Zealand Trust, Meriel Watts of Pesticide Action Network Aotearoa New Zealand, Peter Bankers, Patricia Holborow, Steffan Browning of Soil & Health Association of New Zealand) were in favour of an immediate ban on all uses of endosulfan in New Zealand. The Committee noted that those submitters supporting a ban on endosulfan use attending the hearing only represented a very small number of the overall number of submitters (182 out of 187 submitters) who supported a ban.

4.4 In relation to those submitters seeking a ban, the Committee especially wishes to thank Dr. Meriel Watts of the Pesticide Action Network for her thorough submissions and presentation of background material. Many of the other submitters (both those present and those who submitted only in written form) relied on the Pesticide Action Network's work in their submissions.

4.5 The Committee was also fortunate to hear from one of the manufacturers, Peter Chalmers of Agronica who stayed throughout the hearing and greatly assisted the Committee in relation to a number of questions and issues that arose. Mr Chalmers also supplied the Committee with a list of the forty seven countries where endosulfan is currently registered.

4.6 From industry the Committee heard from Peter Revington of Meat and Wool New Zealand that they supported an immediate ban of endosulfan due to the enormous damage the residues of the substance have had (and have the potential to have in the future) on our export trade markets.

4.7 Peter Ensor from Horticulture New Zealand supported a phasing out of the use of endosulfan. However, for practical reasons, for example the identification of alternative controls for Australian whitefly on citrus, the industry did not support an immediate ban. Some of the issues raised by Horticulture New Zealand were the issues of disposal of existing stocks of the product, the need for more work to be done on alternatives and the particular needs of the citrus industry in the benefits of endosulfan use against the Australian citrus whitefly. On the latter issue Horticulture New Zealand was supported in its presentation by representatives of the Citrus Growers.

4.8 The Committee wishes to record its sincere thanks to Peter Ensor and the other members of the horticulture industry. Not only did Horticulture New Zealand provide detailed information to the Agency during the preparation for the review, but it continued to provide frank and direct information and advice during the course of the hearing. Mr Ensor's willingness to answer questions, some of which were difficult, is commended by the Committee and it wishes to record its formal thanks to Mr Ensor and his industry for the approach they took in relation to this application.

4.9 Finally, the Committee acknowledges that the submitters made a considerable effort and investment to be involved in the hearing and thanks them all for their attendance and involvement. The Committee appreciates their contributions which are a valuable component of the decision-making process.

# 5 Consideration

## Legislative criteria for application

5.1 In June 2007, the Authority decided that there were grounds for reassessment of endosulfan and endosulfan formulations, because:

- significant new information relating to the effects of endosulfan has become available; and
- other substances with similar or improved beneficial effects and reduced adverse effects were available.

5.2 An application was lodged by the Chief Executive pursuant to section 63 following grounds for reassessment having been established under section 62 by the Authority in its decision dated 19 June 2007.

5.3 This application for the reassessment of endosulfan and substances containing endosulfan was lodged pursuant to section 63 and, as required under that section, deemed to be an application made under section 29. Section 29 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 the substance outweigh the adverse effects of the substance.

5.4 In making this decision the Authority has applied the relevant sections of the Act and followed the relevant provisions of the Methodology as detailed in the decision path attached to this decision as **Appendix 1**.

## Information review

5.5 In the application, the Agency concluded that on the weight of the evidence, the information available to it constituted an adequate and appropriate basis for assessing the risks, costs and benefits associated with endosulfan and formulations containing endosulfan. In the absence of quantitative exposure information, the Agency used qualitative exposure assessment models to determine the levels of risk to human health

and the environment. The Committee notes the uncertainty inherent in these assessments.

5.6 The risk management framework used by the Authority requires consideration of uncertainty. The Authority is required to be mindful of the scale and significance of the risks, costs and benefits when reviewing the information available. In addition, when there is scientific and technical uncertainty or disputed information, the Authority must determine the materiality and relevance of that uncertainty. If such uncertainty cannot be resolved the Authority is required to take into account the need for caution in managing the adverse effects of the substance.

5.7 The Committee has reviewed the available information and is satisfied that the available information is relevant and appropriate and is sufficient to demonstrate that the effects are of a sufficient magnitude to warrant attention under the Act.

5.8 In reviewing the information and reaching its decision the Committee has taken into account the ethical considerations that are associated with endosulfan and formulations containing endosulfan, and in particular those associated with the use of the substances. Specifically the Committee has applied the principles and procedural standards of the ERMA New Zealand Ethics Framework to its consideration of all the information provided.

## Hazard classification

5.9 The Committee noted that the Agency classified endosulfan and formulations containing endosulfan as follows in Table 1 and Table 2:

**Table 1: Summary of hazard classifications for endosulfan**

| Toxicity Classification | Classification | Data triggering classification | Reference |
|---|---|---|---|
| **Acute Oral Toxicity** | 6.1B | SPECIES: Rat<br>ENDPOINT: $LD_{50}$<br>VALUE: 22.7 mg/kg b w | APVMA, 1998 |
| **Acute Dermal Toxicity** | 6.1B[1] | SPECIES: Rat<br>ENDPOINT: $LD_{50}$<br>VALUE: 34 mg/kg b w | Lewis, 1996 |
| **Acute Inhalation Toxicity** | 6.1A | SPECIES: Rat (F)<br>ENDPOINT: $LC_{50}$<br>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 | APVMA, 1998 |

| | | | |
|---|---|---|---|
| | | 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). | |
| **Aquatic ecotoxicity** | 9.1A | freshwater fish 96 hr $LC_{50}$ = 0.2 µg/l<br>freshwater invertebrates48 hr $EC_{50}$ = 0.1 µg/l | most sensitive species ANZECC, 2000 |
| **Soil ecotoxicity** | 9.2A | *Eisenia andrei* (Earthworm)<br>14 day(s) $EC_{50}$ of 0.94 mg/kg-dry-weight-soil | Heimbach, 1985 |
| **Terrestrial vertebrate ecotoxicity** | 9.3A | SPECIES: Rat<br>ENDPOINT: $LD_{50}$<br>VALUE: 22.7 mg/kg b w | APVMA, 1998 |
| **Terrestrial invertebrate toxicity** | 9.4B | SPECIES: Honey bee *Apis mellifera*<br>DURATION: 48 hr<br>ENDPOINT: $LD_{50}$<br>VALUE: 2 µg a.i./bee (oral), 2.4 µg a.i./bee (contact) | APVMA (1998) |

## Table 2: Summary of hazard classifications for endosulfan formulations

| | **Emulsifiable concentrate containing 350 g/l endosulfan** | | | | |
|---|---|---|---|---|---|
| **Toxicity Classification** | **(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 | 6.1A | 6.1A | 6.1A |
| **Overall Acute Toxicity** | 6.1A | 6.1A | 6.1A | 6.1A | 6.1A |
| **Skin Irritation** | 6.3A | 6.3B | 6.3A | 6.3A | 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 |

5.10 The Committee notes that these classifications for endosulfan and endosulfan formulations differ from those of the previously approved substances as a result of a more thorough review by the Agency of the available toxicological and ecotoxicological data.

## Controls

5.11 In the application, the Agency assessed the current controls assigned as part of the existing approvals. These controls were based on the substances' hazardous properties as set out in the HSNO Regulations. These controls were used as a reference for evaluation in the application.

5.12 In the application, the Agency evaluated the risks, costs and benefits in association with the current controls and found that there were significant (non-negligible) risks associated with the use of endosulfan in New Zealand which potentially outweighed the benefits. Noting that it did not at that stage, have sufficient reliable information in order to properly assess or verify benefits of using the substance, the Agency made a number of recommendations including that aerial, domestic and citrus (airblast) application be prohibited, that turf use be restricted and proposing Restricted Entry Intervals (REIs), the setting of maximum application rates, a "no spray" buffer zone and requirements for personal protective equipment (PPE).

5.13 In the application, the Agency noted that the statutory public submission process afforded a further opportunity for information to be provided which could result in the Authority establishing a higher level of benefits.

5.14 Following the receipt of submissions, the Agency reviewed its original recommendations and made a number of revised recommendations in the Update Paper. These included prohibiting aerial, domestic and airblast (citrus) application with either immediate effect or following a very short phase out period. As regards other uses, the Agency noted Horticulture New Zealand's submission proposing a phase out over a five year period and recommended that a tighter risk management regime should be adopted

during any phase out period including, specific REIs and PPE, and a 100m "no spray" buffer zone.

5.15 For the 'off label' turf use, the Agency noted concerns expressed by submitters over the cost-effective application and practicability of the proposed controls, and noted that the Committee could decide to prohibit use on turf outright or phase it out over a period of time. In the case of the latter option, the Agency proposed a maximum application rate of 0.7 kg a.i./ ha, one application per season, immediate watering in and a 48 hour "stand down" period in the case of ground contact sports fields and public parks where children may play.

## Areas of effect

5.16 Based on their hazardous properties and their lifecycles and use patterns, endosulfan and endosulfan formulations have the potential to cause adverse effects to:

- workers involved in the manufacture of the substances;
- workers and bystanders should an incident occur in transportation or storage of the substances;
- users of the substances;
- the public from spray drift;
- the public who use any sports grounds, golf courses or bowling greens that have been treated;
- the public through exposure to residues in food;
- the public through long range transport, through food residues, leading to breast milk and fat tissue residues;
- the environment from spillage, seepage, runoff or long range transport;
- the relationship of Māori to the environment through exposure of water, soil and native flora and fauna to the substances.

## Identification and assessment of the risks, costs and benefits

5.17 In its application for the reassessment of endosulfan and endosulfan formulations, the Agency identified potentially significant and therefore non-negligible risks to the environment, to human health and safety, to the relationship of Māori with the environment and to society and the community.

### ***Environmental risk assessment***

5.18 The following assessments made by the Agency in the application are noted and accepted by the Committee:

- There is a high acute and chronic risk to aquatic species (fish and invertebrates) from all current uses of endosulfan in New Zealand. 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.

- Laboratory data suggest 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 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.
- Contamination of remote regions through long-range movement of endosulfan is likely based on overseas monitoring.

5.19 As required by clause 33 of the Methodology, the Committee considered its approach to risk with respect to the high and chronic risk to aquatic species. Whilst noting that this risk could be reduced by substantial buffer zones, the Committee was of the view that this risk will persist over time and that the potential effects may be irreversible.

***Human health risk assessment***

5.20 The following assessments made in the application are noted and accepted by the Committee:

- Risks to operators involved in mixing, loading and applying endosulfan for outdoor crops (including hand-held application) in accordance with current labelled application rates (0.7 kg a.i./ha) are estimated as acceptable, provided that adequate PPE is used.
- Risks to operators involved in mixing and loading for use in glasshouses are acceptable provided adequate PPE is used (noting that application within the glasshouse is by remote means not involving operator exposures).
- Risks to operators for 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 and the different application method.
- 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 REIs are applied.
- Risks to bystanders and residents are estimated as acceptable for boom application to turf and in accordance with the label uses.
- Risks to bystanders and residents from air-blast application to citrus are estimated as very high.
- Risks to sports people from use of endosulfan on treated turf may be acceptable if application is in accordance with the current standard practices involving watering in and only one annual treatment and an REI is applied.

5.21 Concerns raised about the practicality of the risk mitigation controls recommended have been noted by the Committee. The Committee considers these concerns to be valid and that the human health risks are significant.

5.22 In considering its approach to risk the Committee further notes that exposure to the risk is involuntary in many cases and that it will persist over time.

### *Benefits*

5.23 No potentially significant or non-negligible benefits were identified.

5.24 Some of the available information suggests that endosulfan is an important element in Integrated Pest Management (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.

5.25 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.

5.26 Turf managers have indicated that there are social and economic benefits from the availability of endosulfan for control of earthworms. Endosulfan is required to manage and reduce earthworm numbers on turf and thereby maintain playing quality by reducing the worm casting. Endosulfan is cost effective and turf managers submit that it provides the best control of earthworms. There are social and economic benefits to horticulturalists from knowing that there is a 'last resort' insecticide available, and from the availability of a comparatively cheap and long lasting insecticide.

5.27 One benefit identified, is its use in the control of whitefly by the citrus industry. However, the Committee is of the view that the method of application (airblast) poses a significant risk to the operator and bystanders and greatly outweighs this benefit. The Agency had recommended in the application that the use of endosulfan be prohibited for airblast application and evidence at the hearing confirmed this as the only application method suited to the citrus industry. The Committee is of the view that there are no practical controls that could be added to adequately mitigate this risk to the health of operators and bystanders.

5.28 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, while endosulfan is seen as a cheap and effective product the Committee did not consider that under present use conditions there were any potentially significant benefits from the use of endosulfan.

### *Assessment of any risks costs or benefits to New Zealand's international obligations*

5.29 The committee noted that New Zealand is party to two relevant international conventions, the Stockholm Convention on Persistent organic Pollutants and the Rotterdam Convention on the Prior Informed Consent Procedure for certain hazardous chemicals and pesticides in international trade. The Committee noted as follows:

- In October 2008 endosulfan was accepted into the review process of the Stockholm Convention for Persistent Organic Pollutants (POPs);

- Endosulfan and endosulfan formulations are also under consideration for inclusion under the Rotterdam Convention 'Prior Informed Consent' , but the 4th conference of parties in October 2008 failed to reach consensus on listing in the convention;

5.30 On the basis of these observations the Committee notes that while relevant international obligations are considering endosulfan there are no specific provisions that currently impact on this decision.

***Likely effects of the substances being unavailable***

5.31 The Committee notes that there are alternative products available for most of the current uses for endosulfan in New Zealand.

5.32 Upon reviewing all the information contained in the application and received from submitters and at the hearing, the Committee accepts the Agency's evaluation of the risks to the environment and human health of endosulfan and endosulfan formulations as set out in the application and considers the risks to be high. The Committee has considered its approach to risk and notes that the nature of these risks is such that the Committee believes that there is a need for a risk averse position to be adopted.

5.33 The Committee noted the availability of alternatives to endosulfan and endosulfan formulations for most uses. Horticulture New Zealand and the Citrus Industry Council reported that endosulfan is the only compound that effectively controls broad mite on lemons and is also a possible control option for Australian citrus whitefly, a new pest of citrus.

***An overall evaluation of the combined impact of all of the risks costs and benefits***

5.34 The Committee is required under the Act, to consider 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.

5.35 In addition to the risk averse approach adopted with respect to the risks to the environment and human health, the Committee notes that there is some uncertainty associated with the technical information provided with respect to the risks associated with endosulfan and endosulfan formulations and therefore the Committee has adopted a cautious approach as required by section 7 of the Act.

5.36 Upon reviewing all the information contained in the application and received from submitters and at the hearing, the Committee accepts the Agency's evaluation of the risks to the environment and human health of endosulfan and endosulfan formulations as set out in the application and considers the risks to be high.

5.37 The Committee considers there are significant risks to Māori cultural wellbeing, society and the community and to New Zealand's international relationships.

5.38 The Committee considers that there are no significant benefits associated with the availability of endosulfan and endosulfan formulations.

5.39 Thus, the Committee considers that it is evident that the risks and costs associated with the approval of endosulfan and endosulfan formulations outweigh the benefits.

***Conclusions***

5.40 Taking into account, the approach to risk, the precautionary approach and the effects of the substances being unavailable, the Committee considers that the high level of adverse effects (risks and costs) to the environment, human health, the relationship of Māori to the environment and New Zealand's international relationships outweigh any positive effects (benefits) associated with the availability of endosulfan and endosulfan formulations in New Zealand.

# 6 Decision

6.1 The Committee determines that, pursuant to section 29 and clause 27 the adverse effects of endosulfan and formulations containing endosulfan outweigh the positive effects.

6.2 The Committee:

(a) Declines to approve the further importation or manufacture of endosulfan and formulations containing endosulfan and accordingly revokes the following approvals:

- endosulfan (Approval Number HSR002846);
- emulsifiable concentrate containing 350 g/litre endosulfan (Substance A) (Approval Number HSR000679);
- emulsifiable concentrate containing 350 g/litre endosulfan (Substance B) (Approval Number HSR000678);
- emulsifiable concentrate containing 350 g/litre endosulfan (Substance C) (Approval Number HSR000487);
- emulsifiable concentrate containing 350 g/litre endosulfan (Substance D) (Approval Number HSR000677),

(b) issues a direction prohibiting the use of endosulfan or any of the above formulations for any purpose and imposing controls on the collection and disposal of endosulfan. These controls are attached to this decision as Appendix 3. All endosulfan and formulations containing endosulfan must be disposed of within 12 months of this decision coming into effect.

This decision will come into effect 28 days after the direction is published in the *Gazette*.

6.3 The Committee considers that the decision should be implemented as soon as possible. However, the Committee also recognises that the decision must be communicated before it has effect. For this reason the Committee has directed that the decision should come into effect 28 days after the direction is published in the *Gazette*.

6.4 The Committee notes that an approved method of disposal will be in accordance with the Ministry for the Environment and Regional Council partnership scheme for disposal

of rural hazardous waste (http://www.mfe.govt.nz/issues/waste/special/agrichemicals/index.html).

6.5 This scheme provides a free disposal option for holders of unused stocks of endosulfan formulations but is only currently available through the following regional councils:

- Auckland
- Waikato
- Wellington
- Canterbury
- Otago.

6.6 ERMA New Zealand will be putting out an information sheet on disposal shortly.

6.7 In accordance with clause 36(2)(b), the Committee records that, in reaching these conclusions, it has applied the balancing tests in section 29 and clauses 26 and 27.

6.8 It has also applied the following criteria in the Methodology:

- clause 9 – equivalent of sections 5, 6 and 8;
- clause 11 – characteristics of substance;
- clause 12 – evaluation of assessment of risks;
- clause 13 – evaluation of assessment of costs and benefits;
- clause 14 – costs and benefits accruing to New Zealand;
- clause 21 – the decision accords with the requirements and regulations;
- clause 22 – the evaluation of risks, costs and benefits – relevant considerations;
- clause 24 – the use of recognised risk identification, assessment, evaluation and management techniques;
- clause 25 – the evaluation of risks;
- clause 33 – risk characteristics;
- clause 34 – the aggregation and comparison of risks, costs and benefits;
- clause 35 – the costs and benefits of varying the default controls.

Helen Atkins Date: 10 December 2008

**Chair**

# Appendix 1: Decision path for reassessment of hazardous substances

**Context**

This decision path describes the decision-making process for the application to import and manufacture endosulfan and formulated substances containing endosulfan. This application is made under section 63 (Reassessment) of the HSNO Act, and determined under section 29 of the Act.

**Introduction**

The purpose of the decision path is to provide the Authority with guidance so that all relevant matters in the HSNO Act and the Methodology have been addressed. It does not attempt to direct the weighting that the Authority may decide to make on individual aspects of an application.

In this document 'section' refers to sections of the HSNO Act, and 'clause' refers to clauses of the ERMA New Zealand Methodology.

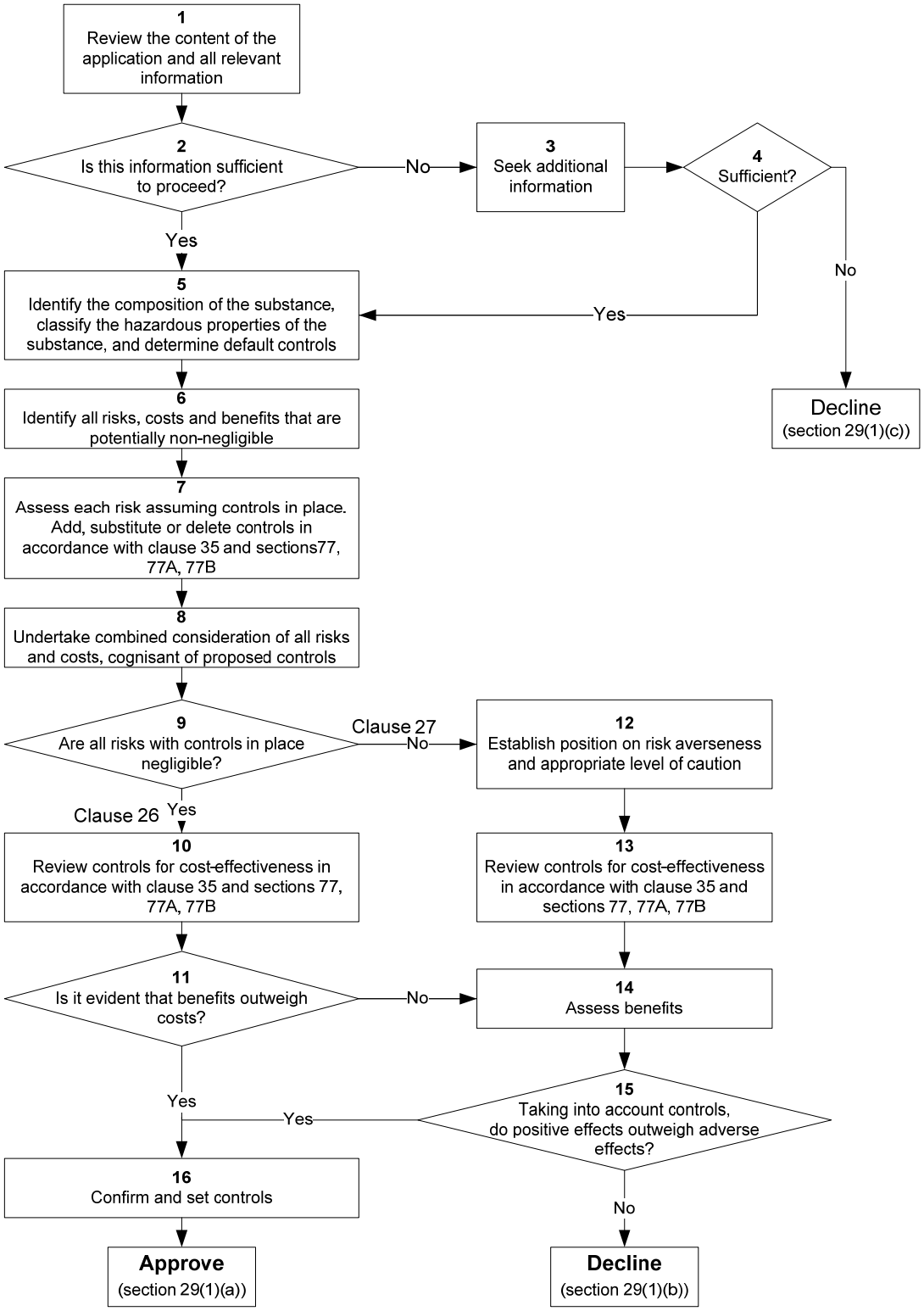
The decision path has two parts –

- **Flowchart** (a logic diagram showing the process prescribed in the Methodology and the HSNO Act to be followed in making a decision), and
- **Explanatory notes** (discussion of each step of the process).

Of necessity the words in the boxes in the flowchart are brief, and key words are used to summarise the activity required. The explanatory notes provide a comprehensive description of each of the numbered items in the flowchart, and describe the processes that should be followed to achieve the described outcome.

**Decision path for applications to import or manufacture a hazardous substance, application made under section 28 of the Act and determined under section 29.**

For proper interpretation of the decision path it is important to work through the flowchart in conjunction with the explanatory notes.



## *Figure 1 EXPLANATORY NOTES*

**Item 1: Review the content of the application and all relevant information**
Review the application, the E&R Report, and information received from experts and that provided in submissions (where relevant) in terms of section 28(2) of the Act and clauses 8, 15, 16 and 20 of the Methodology.

**Item 2: Is this information sufficient to proceed?**
Review the information and determine whether or not there is sufficient information available to make a decision.

The Methodology (clause 8) states that the information used by the Authority in evaluating applications shall be that which is appropriate and relevant to the application. While the Authority will consider all relevant information, its principal interest is in information which is significant to the proper consideration of the application; ie information which is "necessary and sufficient" for decision-making.

**Item 3: (if no) Seek additional information**
If there is not sufficient information then additional information may need to be sought from the applicant, the Agency or other parties/experts under section 58 of the Act (clause 23 of the Methodology).

**Item 4 Sufficient?**
When additional information has been sought, has this been provided, and is there now sufficient information available to make a decision?

If the Authority is not satisfied that it has sufficient information for consideration, then the application must be declined under section 29(1)(c).

**Item 5: (If 'yes' from item 2 or from item 4) Identify the composition of the substance, classify the hazardous properties, and determine default controls**
Identify the composition of the substance, and establish the hazard classifications for the identified substance.

Determine the default controls for the specified hazardous properties using the regulations 'toolbox'.

**Item 6: Identify all risks, costs and benefits that are potentially non-negligible[2]**
Costs and benefits are defined in the Methodology as the value of particular effects (clause 2). However, in most cases these 'values' are not certain and have a likelihood attached to them. Thus costs and risks are generally linked and may be addressed together. If not, they will be addressed separately. Examples of costs

[2] Relevant effects are **marginal effects**, or the changes that will occur as a result of the substance being available. Financial costs associated with preparing and submitting an application are not marginal effects and are not effects of the substance(s) and are therefore not taken into account in weighing up adverse and positive effects. These latter types of costs are sometimes called 'sunk' costs since they are incurred whether or not the application is successful.

that might not be obviously linked to risks are direct financial costs that cannot be considered as 'sunk' costs (see footnote 1). Where such costs arise and they have a market economic effect they will be assessed in the same way as risks, but their likelihood of occurrence will be more certain (see also item 11).

Identification is a two step process that scopes the range of possible effects (risks, costs and benefits).

Step 1: Identify all possible risks and costs (adverse effects) and benefits (positive effects) associated with the approval of the substance(s), and based on the range of areas of impact described in clause 9 of the Methodology and sections 5 and 6 of the Act[3]. Consider the effects of the substance through its lifecycle (clause 11) and include the likely effects of the substance being unavailable (sections 29(1)(a)(iii) and 29(1)(b)(iii)).

Relevant costs and benefits are those that relate to New Zealand and those that would arise as a consequence of approving the application (clause 14).

Consider short term and long term effects.

Identify situations where risks and costs occur in one area of impact or affect one sector and benefits accrue to another area or sector; that is, situations where risks and costs do not have corresponding benefits.

Step 2: Document those risks, costs and benefits that can be readily concluded to be negligible[4], and eliminate them from further consideration.

Note that where there are costs that are not associated with risks some of them may be eliminated at this scoping stage on the basis that the financial cost represented is very small and there is no overall effect on the market economy.

**Item 7: Assess each risk assuming controls in place. Add, substitute or delete controls in accordance with clause 35 and sections 77, 77A and 77B of the Act.**
The assessment of potentially non-negligible risks and costs should be carried out in accordance with clauses 12, 13, 15, 22, 24, 25, and 29 to 32 of the Methodology. The assessment is carried out with the default controls in place.

Assess each potentially non-negligible risk and cost estimating the magnitude of the effect if it should occur and the likelihood of it occurring. Where there are

[3] Effects on the natural environment, effects on human health and safety, effects on Māori culture and traditions, effects on society and community, effects on the market economy.

[4] Negligible effects are defined in the Annotated Methodology as "Risks which are of such little significant in terms of their likelihood and effect that they do not require active management and/or after the application of risk management can be justified by very small levels of benefits.

non-negligible financial costs that are not associated with risks then the probability of occurrence (likelihood) may be close to 1. Relevant information provided in submissions should be taken into account.

The distribution of risks and costs should be considered, including geographical distribution and distribution over groups in the community, as well as distribution over time. This information should be retained with the assessed level of risk/cost.

This assessment includes consideration of how cautious the Authority will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the adverse effect as a means of identifying the range of uncertainty (clause 32). It is also important to bear in mind the materiality of the uncertainty and how significant the uncertainty is for the decision (clause 29(a)).

Consider the Authority's approach to risk (clause 33 of the Methodology) or how risk averse the Authority should be in giving weight to the residual risk, where residual risk is the risk remaining after the imposition of controls.
See ERMA New Zealand report 'Approach to Risk' for further guidance[5].

Where it is clear that residual risks are non-negligible and where appropriate controls are available, add substitute or delete controls in accordance with sections 77 and 77A of the Act to reduce the residual risk to a tolerable level. If the substance has toxic or ecotoxic properties, consider setting exposure limits under section 77B. While clause 35 is relevant here, in terms of considering the costs and benefits of changing the controls, it has more prominence in items 10 and 13

If changes are made to the controls at this stage then the approach to uncertainty and the approach to risk must be revisited.

**Item 8: Undertake combined consideration of all risks and costs, cognisant of proposed controls**

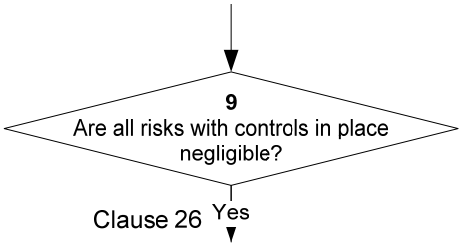
Once the risks and costs have been assessed individually, if appropriate consider all risks and costs together as a 'basket' of risks/costs. This may involve combining groups of risks and costs as indicated in clause 34(a) of the Methodology where this is feasible and appropriate, or using other techniques as indicated in clause 34(b). The purpose of this step is to consider the interactions between different effects and determine whether these may change the level of individual risks.

**Item 9: Are all risks with controls in place negligible?**

Looking at individual risks in the context of the 'basket' of risks, consider whether all of the residual risks are negligible.

[5] http://www.ermanz.govt.nz/resources/publications/pdfs/ER-OP-03-02.pdf

**Item 10:**




**(from item 9 - if 'yes') Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B**

Where all risks are negligible the decision must be made under clause 26 of the Methodology.

Consider the practicality and cost-effectiveness of the proposed individual controls and exposure limits (clause 35). Where relevant and appropriate, add, substitute or delete controls whilst taking into account the view of the applicant, and the cost-effectiveness of the full package of controls.

**Item 11:** **Is it evident that benefits outweigh costs?**

Risks have already been determined to be negligible (item 9). In the unusual circumstance where there are non-negligible costs that are not associated with risks they have been assessed in item 7.

Costs are made up of two components: internal costs or those that accrue to the applicant, and external costs or those that accrue to the wider community.

Consider whether there are any non-negligible external costs that are not associated with risks.

If there are no external non-negligible costs then external benefits outweigh external costs. The fact that the application has been submitted is deemed to demonstrate existence of internal or private net benefit, and therefore total benefits outweigh total costs[6]. As indicated above, where risks are deemed to be negligible, and the only identifiable costs resulting from approving an application are shown to accrue to the applicant, then a cost-benefit analysis will not be required. The act of an application being lodged will be deemed by the Authority to indicate that the applicant believes the benefits to be greater than the costs.

However, if this is not the case and there are external non-negligible costs then all benefits need to be assessed (via item 14).

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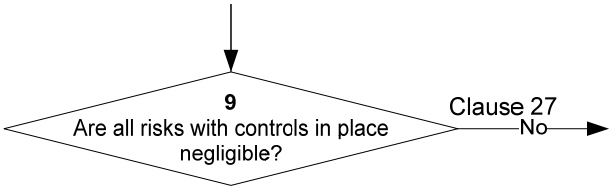
[6] Technical Guide 'Risks, Costs and Benefits' page 6 - Note that, where risks are negligible and the costs accrue only to the applicant, no explicit cost benefit analysis is required. In effect, the Authority takes the act of making an application as evidence that the benefits outweigh the costs". See also Protocol Series 1 'General requirements for the Identification and Assessment of Risks, Costs, and Benefits'.

**Item 12:**




**(from item 9 - if 'no') Establish Authority's position on risk averseness and appropriate level of caution**

Although 'risk averseness' (approach to risk, clause 33) is considered as a part of the assessment of individual risks, it is good practice to consolidate the view on this if several risks are non-negligible. This consolidation also applies to the consideration of the approach to uncertainty (section 7)

**Item 13:** **Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B**

This constitutes a decision made under clause 27 of the Methodology (taken in sequence from items 9 and 12).

Consider whether any of the non-negligible risks can be reduced by varying the controls in accordance with sections 77 and 77A of the Act, or whether there are available more cost-effective controls that achieve the same level of effectiveness (section 77A(4)(b) and clause 35(a)).

Where relevant and appropriate, add, substitute or delete controls whilst taking into account the views of the applicant (clause 35(b)), and making sure that the total benefits that result from doing so continue to outweigh the total risks and costs that result.

As for item 7, if the substance has toxic or ecotoxic properties, consider exposure limits under section 77B.

**Item 14:** **(if 'no' from item 11 or in sequence from item 13) Assess benefits**

Assess benefits or positive effects in terms of clause 13 of the Methodology.

Since benefits are not certain, they are assessed in the same way as risks. Thus the assessment involves estimating the magnitude of the effect if it should occur and the likelihood of it occurring. This assessment also includes consideration of the Authority's approach to uncertainty or how cautious the Authority will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the positive effect.

An understanding of the distributional implications of a proposal is an important part of any consideration of costs and benefits, and the distribution of benefits should be considered in the same way as for the distribution of risks and costs. The Authority will in particular look to identify those situations where the beneficiaries of an application are different from those who bear the costs[7]. This is important not only for reasons related to fairness but also in forming a view of just how robust any claim of an overall net benefit might be. It is much more difficult

[7] This principle derives from Protocol Series 1, and is restated in the Technical Guide 'Risks, Costs and Benefits'.

to sustain a claim of an overall net benefit if those who enjoy the benefits are different to those who will bear the costs. Thus where benefits accrue to one area or sector and risks and costs are borne by another area or sector then the Authority may choose to be more risk averse and to place a higher weight on the risks and costs.

As for risks and costs, the assessment is carried out with the default controls in place.

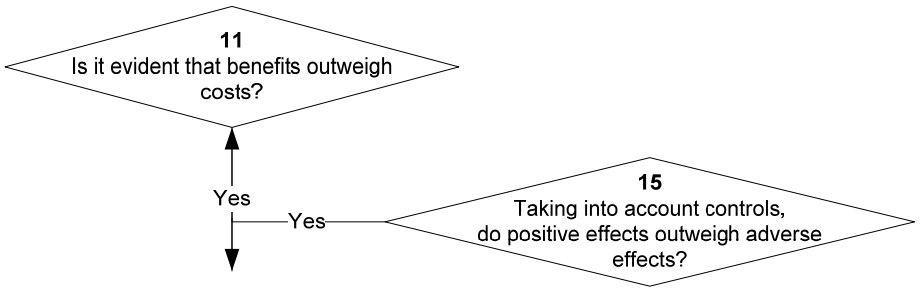
**Item 15:** **Taking into account controls, do positive effects outweigh adverse effects?**

In weighing up positive and adverse effects, consider clause 34 of the Methodology. Where possible combine groups of risks, costs and benefits or use other techniques such as dominant risks and ranking of risks. The weighing up process takes into account controls proposed in items 5, 7, 10 and/or 13.

Where this item is taken in sequence from items 12, 13 and 14 (i.e. risks are not negligible) it constitutes a decision made under clause 27 of the Methodology.

Where this item is taken in sequence from items 9, 10, 11 and 14 (i.e. risks are negligible, and there are external non-negligible costs) it constitutes a decision made under clause 26 of the Methodology.

**Item 16:**




**(if 'yes' from items 11 or 15) Confirm and set controls**

Controls have been considered at the earlier stages of the process (items 5, 7, 10 and/or 13). The final step in the decision-making process brings together all the proposed controls, and reviews them for overlaps, gaps and inconsistencies. Once these have been resolved the controls are confirmed.

# Appendix 2: Names of those who made oral presentations at the hearing

| Submission number | Submitter |
|---|---|
| **Day 1 (20 October 2008)** | |
| 10162 | Andrew Mitchell, New Zealand Sports Turf Institute |
| 10143 | Elizabeth Harris |
| | Expert witnesses: |
| | Mike Eccles |
| | David McBride |
| | Alison Roe |
| 10180 | Donna Bird, Many Affected Friends of Aotearoa (MAFIA) |
| 10235 | Peter Revington, Meat and Wool New Zealand |
| 10247 | Peter Chalmers, Agronica New Zealand Ltd |
| 10236 | Catherine Delahunty |
| 10252 | Sue Kedgley, Green Party of Aotearoa New Zealand |
| 10250 | Alison White, Safe Food Campaign |
| 10144 | Alison White on behalf of Jacqui Knight, Monarch Butterfly New Zealand Trust |
| **Day 2 (21 October 2008)** | |
| 10239 | Meriel Watts, Pesticide Action Network Aotearoa New Zealand |
| 10034 | Peter Bankers |
| 10058 | Patricia Holborow |
| 10244 | Steffan Browning, Soil & Health Association of New Zealand |
| 10241 | Peter Ensor, Horticulture New Zealand |
| 10246 | Simon Terry, Sustainability Council of New Zealand |

# Appendix 2: Controls on the disposal and collectors of endosulfan

**Controls on the disposal of endosulfan**

1. Endosulfan may be disposed of by –

(a) by treating the substance using a method that changes the characteristics or composition of the substance so that the substance or any product of such treatment is no longer a hazardous substance; or

(b) by exporting the substance from New Zealand as waste for environmentally sound disposal provided that such export complies with the relevant requirements of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal and the OECD Decision C(2001)107 on the Control of Transboundary Movement of Wastes Destined for Recovery Operations.

2. In subclause (1)(a), treating the substance does not include—

(a) application to or discharge to any environmental medium; or

(b) dilution of the substance with any other substance before discharge into the environment; or

(c) depositing the substance in a landfill or a sewage facility; or

(d) depositing the substance in an incinerator unless in doing so the substance is treated in accordance with subclause (1)(a).

**Controls on collectors of endosulfan**

3. For formulations that have a class 3 hazard classification a collector must comply with the controls in the Hazardous Substances (Classes 1 to 5 Controls) Regulations 2001.

4. A collector must ensure that equipment used to handle the substance complies with regulation 7 of the Hazardous Substances (Class 6, 8, and 9 Controls) Regulations 2001.

5. A collector who handles endosulfan must comply with regulation 8 of the Hazardous Substances (Class 6, 8, and 9 Controls) Regulations 2001.

6. Regulation 9 of the Hazardous Substances (Class 6, 8, and 9 Controls) Regulations 2001 applies to any quantity of endosulfan.

7. For the purposes of regulation 10 of the Hazardous Substances (Class 6, 8, and 9 Controls) Regulations 2001, no endosulfan in any quantity may be carried on any passenger service vehicle.

8. When stored for the purpose of environmentally sound disposal, endosulfan must not be mixed with any other substance.

9. The Hazardous Substances (Packaging) Regulations 2001 apply to endosulfan as if they are deemed to have a hazard classification that is class 6.1B.Transport of endosulfan by land within New Zealand shall comply with all relevant requirements of the Land Transport Rule: Dangerous Goods 1999 (Rule 45001).

10. Transport of endosulfan by sea within New Zealand shall comply with all relevant requirements of either the Maritime Rules: Part 24A – Carriage of Cargoes – Dangerous Goods (MR024A) or the International Maritime Dangerous Goods Code.

11. Transport of endosulfan by air within New Zealand shall comply with all relevant requirements of Part 92 of the Civil Aviation Rules.

12. The Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004 apply to endosulfan stored or transported in a tank, tank wagon or transportable container as those terms are defined in those regulations.

13. The location and movement of endosulfan must be recorded in accordance with the Hazardous Substances (Tracking) Regulations 2001.

14. The Hazardous Substances (Emergency Management) Regulations 2001 apply to endosulfan as if they are deemed to have hazard classifications that are class 6.1A and 9.1A.

15. The Hazardous Substances (Identification) Regulations 2001 apply to endosulfan as if they are deemed to have hazard classifications that are class 6.1A and 9.1A.

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