# Environmental Risk Management Authority Decision

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

Name of substances: Trichlorfon and trichlorfon-containing substances

**Application Number: HRC08005**

**18 February 2011**

# Contents

# 1 Summary of decision

1.1.1 Following consideration of the application for reassessment, the Committee:

(a) **declines** the further importation, manufacture or use from 1 June 2011 of:
- **Emulsion (oil in water) containing 500 g/litre trichlorfon (Approval Number HSR000204)**; and
  **Emulsifiable concentrate (micro emulsion) containing 20 g/litre cypermethrin and 400 g/litre trichlorfon (Approval Number HSR000205)**; and

(b) **approves** the importation, manufacture or use of **trichlorfon (Approval Number HSR002885)** in accordance with the controls set out in Approval Number HSR002885, or the controls set out in **Appendix B** of this approval until 1 June 2011; and

(c) **approves** the importation, manufacture or use of **solid containing 950-990 g/kg trichlorfon (Approval Number HSR1951)** in accordance with the controls set out in Approval Number HSR001951, or the controls set out in **Appendix B** of this approval until 1 June 2011; and

(d) **approves** the importation, manufacture or use of **trichlorfon** and **solid containing 950-990 g/kg trichlorfon** in accordance with the controls set out in **Appendix B** of this approval from 1 June 2011 onwards.

1.1.2 Any existing stocks of the substances identified in paragraph 1.1.1(a) must be used, or disposed of in accordance with the storage and disposal controls set out in the approval under which they were manufactured or imported by 1 June 2011.

# 2 Background to use of trichlorfon in New Zealand

2.1.1 This decision should be read in conjunction with the reassessment application of ERMA New Zealand ("the Agency"), dated 20 July 2010 and the subsequent update paper provided to the decision making committee of the Authority ("the Committee") prior to the consideration of the application. The update paper summarised the submissions and new information received following public notification of the application.

2.1.2 Trichlorfon is a broad-spectrum organo-phosphate insecticide component. Formulations containing trichlorfon have been registered for use in New Zealand since 1968. Currently, trichlorfon and three trichlorfon formulations are approved under section 29 of the Hazardous Substances and New Organisms (HSNO) Act 1996 ("the Act"):

- trichlorfon (approval number HSR002885);
- emulsion (oil in water) containing 500 g/litre trichlorfon (approval number HSR000204);
- emulsifiable concentrate (micro emulsion) containing 20 g/litre cypermethrin and 400 g/litre trichlorfon (approval number HSR000205);
- solid containing 950-990 g/kg trichlorfon (approval number HSR001951).

2.1.3 Trichlorfon has been used on a variety of crops in New Zealand as a plant protection product to control a number of insecticide pests, detailed in **Table 1**:

**Table 1. Plant protection uses of trichlorfon-containing substances.**

| Used on: | To control: |
|---|---|
| Cereal,<br>Pasture<br>Grass Seed | Army Caterpillar |
| Maize<br>Sweetcorn | Corn Earworm |
| Brassicas<br>Tomatoes | Cutworm |
| Brassicas | Diamond-back Moth |
| Beans<br>Tomatoes | Green Vegetable Bug |
| Pasture | Porina |
| Tomatoes | Tomato Fruit Worm |
| Brassicas | White Butterfly |

2.1.4 Trichlorfon has also been used on a variety of animals in New Zealand as a veterinary medicine to control a number of insecticide pests, detailed in **Table 2**:

**Table 2. Veterinary medicine uses of trichlorfon-containing substances.**

| Used on: | To control: |
|---|---|
| Horse | Bots (*Gastrophilus* spp.) and Ascarids |
| Sheep | *Oestrus ovis* (Nasal Bots) *Haemonchus* |
| Pigs | Roundworms (Ascarids)<br>Whipworms (*Trichuris suis*)<br>Lice<br>*Haematopinus suis*<br>Sarcoptic mange<br>*Sarcoptes scabiei* |
| Poultry | Lice<br>Red Mites<br>*Dermanyssus gallinae* |

2.1.5 Trichlorfon products have been reviewed in the following countries or jurisdictions: United State (US EPA), Europe (EU), Canada (PMRA). These reviews have resulted in restrictions, prohibitions or voluntary removal from the market.

2.1.6 In the application for reassessment, the Agency recommended that the approvals for plant protection products containing trichlorfon should be declined, on the basis that the risks associated with the plant protection use of trichlorfon-containing substances in New Zealand outweigh the benefits of use. The key risks of concern identified in the application relate to the high risks to the environment, for which the Agency considers there are no appropriate management options except for discontinuation of the approvals.

2.1.7 The Agency also recommended that the existing approvals for veterinary medicine products containing trichlorfon should be revised to include additional controls in order to manage the risks posed to human health. The additional controls proposed by the Agency recognised that most of the human health risks could be managed by prescribing Personal Protective Equipment (PPE), and restricting how the substance can be used.

2.1.8 The Agency evaluated the impact of declining continued use of the approvals in terms of the availability of alternatives and the hazard profile of those alternatives. This evaluation has shown that there are potential alternatives available for all current uses and that at least some of these alternatives are less hazardous than trichlorfon. Based on information received in the submissions, the Agency revised its original proposal and recommended a three month phase-in for the implementation of the outcomes of the decision from the date of this decision. This time period was considered sufficient to provide anyone with stocks of trichlorfon enough disposal time. The Committee notes that the substances may be disposed of through use.

2.1.9 The Committee is also aware that the outcomes of this reassessment may impact on other parties, such as other regulatory bodies. A phase-in period will enable those affected parties to take the actions required by the outcomes of this reassessment.

# 3 The reassessment of trichlorfon and formulations containing trichlorfon

## 3.1 Grounds

3.1.1 Trichlorfon was placed on the Chief Executive Initiated Reassessment (CEIR) Priority List in 2007, taking into account:

- Trichlorfon has the potential to cause adverse effects to the nervous system in humans at low concentrations.
- Trichlorfon is also very ecotoxic in the aquatic environment.
- The US has imposed a series of new and more stringent measures to mitigate the risks of trichlorfon (US EPA, 2006a).
- Submissions on the consultation of the proposed substances indicated that trichlorfon should be on the CEIR priority list.

3.1.2 On 19 August 2008 the Chief Executive of ERMA New Zealand submitted an application to establish whether there were sufficient grounds to justify a reassessment of trichlorfon and its formulations.

3.1.3 On 4 September 2008 the Authority decided that there were grounds for reassessment of trichlorfon and its formulations, based on section 62 of the Act, and noted that:

- formulations containing trichlorfon have been registered for use in New Zealand since 1968. Currently, one product is registered for use in New Zealand as a veterinary medicine (Neguvon 98%) and one as a plant protection product (Trifon);
- overseas regulatory action has led to the withdrawal/phasing out of trichlorfon in Europe, the adoption of more stringent measures for domestic and agricultural use in the USA, and proposals to phase out certain uses in Canada.
- the reassessment of trichlorfon and its formulations aligns with the principles of the ERMA New Zealand Risk Reduction strategy.

## 3.2 The application

3.2.1 An application for the reassessment of trichlorfon and its formulations was prepared by the staff of the Agency on behalf of the Chief Executive under section 63 of the Act.

3.2.2 The Agency sought information from a wide range of sources in the preparation of the application, mainly in respect of the New Zealand lifecycle and use of trichlorfon-containing substances and benefits associated with their use.

3.2.3 The Agency also commissioned reports from:

- Dr Martin Edwards of Toxicology Consulting Limited (a review of the toxicological hazard profile and the current HSNO class 6 and 8 classifications

for trichlorfon and its formulations; and a report on the human health exposure assessment from use of trichlorfon substances);

- Plant and Food Research ( the use of trichlorfon in New Zealand, addressing issues related to the use patterns, including 'off label' uses, benefits from the use of the substance in New Zealand, lifecycle information and availability of alternatives).

3.2.4 In addition, the Agency considered publicly available sources of toxicology and environmental fate and effects test data, studies and other references relating to trichlorfon-containing substances and potential alternatives.

3.2.5 The Chief Executive formally submitted the application for reassessment on 20 July 2010.

## 3.3 Legislative basis

3.3.1 The application for the reassessment of trichlorfon and formulations containing trichlorfon was lodged pursuant to section 63 of the Act and, as required under the Act, the application for reassessment was deemed to be an application made under section 29. Section 29 requires the Authority to consider adverse and positive effects of a substance and to make a decision based on whether or not the positive effects of the substance outweigh the adverse effects of the substance.

3.3.2 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 set out in **Appendix A** to this decision.

3.3.3 References made to a section in this document mean that section of the Act, references to a clause refers to the relevant clause in the Methodology[1].

## 3.4 Timeline

3.4.1 The timeline for the application was as detailed in **Table 3**:

**Table 3. Timeline for the application for the reassessment of trichlorfon**

| Action | Date |
|---|---|
| Application formally received | 20 July 2010 |
| Application publicly notified | 21 July 2010 |
| Public submissions closed | 1 September 2010 |
| Update paper circulated | 15 December 2010 |
| Consideration commenced | 6 January 2011 |

## 3.5 Time limits and waivers

3.5.1 Under section 59, the Committee waived the statutory time limits for the requirement to fix a hearing date within 30 days after the closing date for submissions, pending finalisation of the Agency's review of the submissions. Consideration of the

[1] Hazardous Substances and New Organisms (Methodology) Order 1998

application commenced on 6 January 2011.

## 3.6 Māori interests and concerns

3.6.1 As required by Sections 6(d) and 8 of the Act, the Committee's decision making takes into account the relationship of Māori and their culture and traditions with their ancestral lands, water and other taonga, as well as the principles of the Treaty of Waitangi (Tiriti ō Waitangi).

## 3.7 Ministerial call-in

3.7.1 The Minister for the Environment was advised of the application on 21 July 2010 (under section 53(4)(a)) and given the opportunity to "call-in" the application under section 68. This action was not initiated.

## 3.8 Notification of the application

3.8.1 In accordance with section 53, the application was publicly notified on the ERMA New Zealand website on 21 July 2010 and advertised in the New Zealand Herald, the Dominion Post, the Christchurch Press and the Otago Daily Times

3.8.2 The application summary was also sent to government agencies which were identified as having a specific interest in the application and interested parties who had indicated that they wished to be notified of applications of this type.

## 3.9 Public submissions

3.9.1 A total of six public submissions were received on the trichlorfon application. A summary of the submissions received is set out in the **Appendix** to the update paper.

## 3.10 Appointment of the committee

3.10.1 The following members of the Authority were appointed to consider the application (in accordance with a delegation under section 19(2)(b)): Dr Max Suckling (Chair) and Dr Deborah Read.

## 3.11 Update paper

3.11.1 The Agency prepared an update paper to provide the Committee and submitters with a review of the submissions received in response to the public notification of the reassessment application.

3.11.2 In preparing this paper, the Agency reviewed all the submissions and prepared responses to the significant issues.

3.11.3 The submissions received did not alter the Agency's proposals, except to include a phase-in period for the implementation of the revised controls, which was not included in the Agency's reassessment application.

3.11.4 The update paper was circulated on 15 December 2010.

### 3.12 Information available for the consideration

3.12.1 The Committee had available for its consideration the application, the update paper, and the written submissions.

3.12.2 The Committee is satisfied that it had sufficient information, both relevant and appropriate to the risks, costs and benefits of the substances to enable it to consider the application (clause 8).

## 4 Sequence of the consideration

4.1.1 In accordance with the Methodology, and as outlined in the decision path used by the Committee (set out in **Appendix A**), the approach to the consideration adopted by the Committee was to:

- review the available information (clause 8);
- establish the hazard classifications for each substance and derive the default controls that are prescribed under section 77 for each classification;
- identify potentially significant risks, costs, and benefits (covered by clauses 9 and 11);
- assess the potentially significant risks and costs (risks were assessed in accordance with clause 12, and costs in accordance with clause 13) using recognised techniques (clause 24). The adequacy of the default controls, prescribed under section 77 was considered alongside the assessment of risks and costs to determine whether those controls should be varied and identify where additional controls need to be applied, under section 77A, to mitigate any unacceptable risks;
- consider all the risks and costs and determine whether the individual risks and costs (when combined) are negligible or non-negligible;
- review any non-negligible residual risks and determine whether the decision should follow clause 26 or clause 27;
- establish the approach to risk with respect to the individual non-negligible risks in accordance with clause 33;
- consider (a) whether any of the non-negligible risks could be reduced by varying the controls in accordance with sections 77 or 77A, and (b) the cost-effectiveness of the application of controls in accordance with clause 35 and sections 77 and 77A;
- assess the benefits associated with this application in accordance with clauses 9, 11, 13 and 14 and section 6(e);
- taking into account the risk characteristics established under clause 33, weigh up the risks, costs and benefits in accordance with clause 26 or clause 27 and clause 34 and section 29 taking into account aspects of uncertainty (clauses 29, 30 and 32) and determine whether the application should be approved or declined; and
- confirm and set the controls.

# 5 Ethical considerations

5.1.1 In preparing this decision, the Committee has taken into account the ERMA New Zealand ethics framework. This framework was developed as a tool to assist in the ERMA New Zealand decision-making process in terms of:

- asking the 'right' questions in order to identify ethical issues that need to be considered; and
- using the answers to those questions to explore how ethical considerations should be addressed.

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

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

5.1.3 Under these general principles lies a set of specific principles which includes concern for animal welfare, concern for co-operation, concern for cultural identity, concern for sustainability and concern for peoples' wellbeing.

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

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

5.1.5 In its consideration, the Committee has been mindful of the criteria in the procedural standards listed above, and has reviewed all of the information made available to it in the context of the principles and procedural standards. The Committee has been respectful of the views expressed by the applicant and submitters.

# 6 Treaty of Waitangi

## 6.1 Principles of the Treaty of Waitangi

6.1.1 All persons exercising powers and functions under the Act are required (under section 8) to take into account the principles of the Treaty of Waitangi (Tiriti ō Waitangi). The Authority has developed the Protocol "Incorporating Māori Perspectives in Part V Decision Making" to provide some guidance in the consideration.

6.1.2 Iwi/Māori interests have not been specifically consulted in the preparation of this application. However ERMA New Zealand 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 highly hazardous substances. It is likely that, in the absence of further information regarding benefits, submissions from Māori would generally seek the revocation of the approvals for trichlorfon and its approved formulations.

## 6.2 Active protection

6.2.1 Of particular relevance to this application is the principle of active protection affirmed by the Court of Appeal in the *Lands* case (1987).

6.2.2 This principle 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 Maori people in the use of their lands and waters to the fullest extent practicable.

6.2.3 Taking into account the principle of active protection requires this application to provide sufficient evidence to show that the use of trichlorfon and its approved formulations pose no risk of adverse effects to native/endemic species and/or other taonga species, ecosystems and traditional Māori values, practices, health and well-being. Having considered the information available in relation to the adverse effects noted above, given the recommendations made and controls outlined in this decision the Committee considers that the implementation of this principle is provided for.

# 7 The substances

7.1.1 The reassessment application relates to four existing approvals granted under the Act for trichlorfon and its formulations. These approvals and their related registrations under the Agricultural Compounds and Veterinary Medicines Act 1996 (ACVM Act) are shown in **Table 4** as follows:

**Table 4. Trichlorfon-based products with HSNO approvals**

| Substance description | Approval # | Trade names | ACVM Approval |
|---|---|---|---|
| Trichlorfon [CAS #52-68-6]<br>(active ingredient) | HSR002885 | - | - |
| Emulsifiable concentrate (micro emulsion) containing 20 g/litre cypermethrin and 400 g/litre trichlorfon<br>(plant protection product) | HSR000205 | - | - |
| Emulsion (oil in water) containing 500 g/litre trichlorfon<br>(plant protection product) | HSR000204 | Trifon | A001077 |
| Solid containing 950 - 990 g/kg trichlorfon<br>(veterinary medicine) | HSR001951 | Neguvon 98% | P004686 |

7.1.2 Only two trichlorfon-containing products are currently available in New Zealand:

- Trifon is an oil-in-water emulsion containing 500 g / L trichlorfon, marketed for the control of chewing insects in pasture and some caterpillars, moths and worms in horticultural and agricultural use;
- Neguvon 98% is soluble powder containing 970 g / kg trichlorfon, marketed for use as an antiparasiticide for internal and external application, for the control of bots and ascarids in horses, nasal bot and Barbers Pole worm in sheep, roundworms, lice, sarcoptic mange in pigs, and lice and red mites on poultry.

7.1.3 The Committee notes the information provided in Section 3.7 of the Agency's reassessment application regarding the lifecycles of trichlorfon-containing products:

- Trichlorfon is not currently used in the manufacture of insecticide products in New Zealand.
- Trichlorfon was previously imported into New Zealand to manufacture the product Trifon. However, the registrant has indicated that, once existing stocks of the product are exhausted, they do not wish to continue to market it and will not seek to import any further supplies of trichlorfon.

- Formulations containing trichlorfon are currently labelled for use as plant protection products for a range of pests on cereals, pasture and some vegetables (Table 1), or as veterinary medicines (Table 2).
- A review of current use suggests that trichlorfon is little used for plant protection purposes.
- The registrant of Neguvon 98% has indicated that small quantities of the product are sold each year and that it intends to remove this product from the New Zealand market and therefore further importation of Neguvon 98% is not required.

7.1.4 Although not all approved substances are currently available, given that approvals are not specific to a particular party, assessment of approvals for all trichlorfon-containing substances was undertaken, in case of future use of these approvals to import or manufacture trichlorfon-containing substances.

# 8 Hazard classifications

8.1.1 In the reassessment application, the Agency provided a review of the HSNO classifications for trichlorfon and its formulations. As a result of the review, the Agency proposed the following changes to the classification of trichlorfon:

- Acute dermal toxicity - change from 6.1D to 6.1E;
- Carcinogenicity – introduce 6.7B classification;
- Reproductive/ developmental toxicity - trichlorfon should no longer be classified as a class 6.8 toxicant (current classification is 6.8B);
- Terrestrial invertebrate ecotoxicity – change from 9.4C to 9.4B.

8.1.2 As a result of the changes to the classification of trichlorfon, the classifications of the trichlorfon-containing substances should be changed as follows:

- **Emulsion (oil in water) containing 500 g/litre trichlorfon**
  - Acute oral toxicity - change from 6.1C to 6.1D;
  - Acute dermal toxicity - remove 6.1E classification;
  - Carcinogenicity – introduce 6.7B classification;
  - Reproductive/ developmental toxicity - remove 6.8B classification;
  - Terrestrial invertebrate ecotoxicity – change from 9.4C to 9.4B.
- **Emulsifiable concentrate (micro emulsion) containing 20 g/litre cypermethrin and 400 g/litre trichlorfon**
  - Acute dermal toxicity - remove 6.1E classification;
  - Carcinogenicity – introduce 6.7B classification.
- **Solid containing 950-990 g/kg trichlorfon**
  - Acute dermal toxicity – change from 6.1D to 6.1E;
  - Carcinogenicity – introduce 6.7B classification;

- Reproductive/ developmental toxicity - remove 6.8B classification;
- Terrestrial invertebrate ecotoxicity – change from 9.4C to 9.4B.

8.1.3 The Committee agrees with the proposed changes, but notes that not all of the approvals for trichlorfon-containing substances will be retained (refer to Section 12 below).

8.1.4 The Committee has adopted the Agency's revised classifications for trichlorfon and formulations containing trichlorfon, detailed in **Table 5**:

**Table 5. Classification of trichlorfon and its formulations**

| Hazard Class/Subclass | Trichlorfon (Approval # HSR002885) | Emulsion (oil in water) containing 500 g/litre trichlorfon (Approval # HSR000204) | Emulsifiable concentrate (micro emulsion) containing 20 g/litre cypermethrin and 400 g/litre trichlorfon (Approval # HSR000205) | Solid containing 950-990 g/kg trichlorfon (Approval # HSR001951) |
|---|---|---|---|---|
| Flammability | No | 3.1D | 3.1D | No |
| Acute toxicity (oral) | 6.1C | 6.1D | 6.1C | 6.1C |
| Acute toxicity (dermal) | 6.1E | No | No | 6.1E |
| Acute toxicity (inhalation) | 6.1D | 6.1D | No | 6.1D |
| Eye irritancy/corrosion | 6.4A | 6.4A | 6.4A | 6.4A |
| Contact sensitisation | 6.5B | 6.5B | 6.5B | 6.5B |
| Mutagenicity | 6.6B | 6.6B | 6.6B | 6.6B |
| Carcinogenicity | 6.7B | 6.7B | 6.7B | 6.7B |
| Reproductive/developmental effects | No | No | 6.8B | No |
| Target organ systemic toxicity | 6.9A | 6.9A | 6.9A | 6.9A |
| Aquatic ecotoxicity | 9.1A | 9.1A | 9.1A | 9.1A |
| Soil ecotoxicity | 9.2B | 9.2B | 9.2B | 9.2B |
| Terrestrial vertebrate ecotoxicity | 9.3A | 9.3A | 9.3A | 9.3A |
| Terrestrial invertebrate ecotoxicity | 9.4B | 9.4B | 9.4A | 9.4B |

# 9 Identification of adverse effects, costs and benefits

9.1.1 The Committee agrees with the Agency's assessment of the risks posed throughout the lifecycle phases of trichlorfon and trichlorfon-containing substances. The Agency identified a number of significant adverse effects that it considers are not adequately controlled by the existing management regime (Section 4 of the reassessment application). The risks and benefits that may arise from continued availability and use of trichlorfon are summarised as follows:

- the risks from the use of trichlorfon as a plant protection product are **non-negligible** for the aquatic environment, birds, bees / non-target invertebrates, re-entry by operators and to bystanders, and cannot be reduced to negligible by the application of practicable additional controls to the existing approvals;
- the risks from the use of trichlorfon as a veterinary medicine are **non-negligible** to operators from spray application and subsequent re-entry; but can be reduced to **negligible** by the application of practicable controls to the existing approvals. However, the Committee notes that spray application onto animals is not permitted, and a control is required to restrict the application method;
- no positive effects on the environment or human health.

9.1.2 The Committee agrees with the Agency's assessment of the risks and benefits posed to society and communities and notes that the use of trichlorfon does not offer any significant benefits.

9.1.3 The Committee agrees with the Agency's assessment of the risks and benefits posed to the market economy and that the continued availability and use of trichlorfon does not offer any significant risk or benefit to the market economy, but notes that trichlorfon provides a treatment for lice and red mites on poultry, for which industry has indicated there is no alternative treatment. However, the current level of usage is low.

# 10 Alternatives

10.1.1 In the reassessment application, the Agency reviewed the potential alternatives to trichlorfon substances for plant protection and veterinary medicine uses and concluded that alternatives exist for plant protection use, but effective alternatives for all veterinary medicine uses have not been identified (i.e. for red mite control).

10.1.2 Information received via a submission indicates that there are no registered alternatives currently available for red mite control, but that alternative means may be suitable (such as mechanical cleaning or use of alternative, unregistered products).

# 11 International obligations

11.1.1 Section 6(f) of the Act requires the Committee to take into account New Zealand's international obligations.

11.1.2 The Committee notes that the Agency did not identify any international obligations with regard to trichlorfon.

# 12 Controls

12.1.1 In the application, the Agency assessed the appropriateness of the existing controls assigned as part of the existing approvals. These controls comprise the default controls assigned to the substances based on their hazardous properties and variations and additions to these controls which were applied at the time of transfer from control under the Pesticides Act 1979 and Pesticides (Vertebrate Pest Control) Regulations 1983 to the framework of the HSNO Act. These controls were used as a reference for evaluation in the application.

12.1.2 Under section 77(4) of the Act, the Authority may substitute or delete controls prescribed for classifications. The Authority must be satisfied that—

(a) the adverse effects identified for a substance are less than the adverse effects which would usually be associated with substances given that hazard classification; or

(b) where the benefits of any substance are such that the controls should be varied to retain the benefits and the variation would, in the opinion of the Authority, not significantly increase the adverse effect.

12.1.3 Under section 77A of the Act, the Authority may impose as controls any obligations and restrictions as the Authority thinks fit. Under section 77A(4), the Authority must be satisfied that, against any other specified controls that apply to the substance—

(a) the proposed control is more effective in terms of its effect on the management, use and risks of the substance; or

(b) the proposed control is more cost-effective in terms of its effect on the management, use and risks of the substance; or

(c) the proposed control is more likely to achieve its purpose.

## 12.2 Changes to controls on trichlorfon and trichlorfon-containing substances

12.2.1 The variations to the controls for trichlorfon and trichlorfon-containing substances are detailed in **Table 6**:

**Table 6. Details of additions, deletion and variations made to controls for trichlorfon and trichlorfon-containing substances.**

<table>
<tr><th>Substance / Approval #</th><th>Nature of amendment</th><th>Description of amendment</th><th>Comment and justification</th></tr>
<tr><td rowspan="2">Trichlorfon<br>HSR002885</td><td>Additional control</td><td>The following additional control is applied:<br><br>Prohibition on use of trichlorfon<br>No person may use trichlorfon for any purpose other than as an ingredient or component in the manufacture of a veterinary medicine.</td><td>This control prohibits the use of trichlorfon for any purpose other than a veterinary medicine. The Committee considers that, as the high level of risk associated with use in plant protection products is eliminated, this control is more effective in its effect on the management, use and risks of the substance, than the existing controls (section 77A(4)(a)).<br><br>This additional control effectively means that trichlorfon is not permitted to enter the outdoor environment (unless it is in a formulated substance containing trichlorfon for use as a veterinary medicine with its own approval under the Act).<br><br>The current control includes details allowing the use of trichlorfon for the purposes of research and development, but excludes “laying investigation or experimentation in which the substance is discharged, laid or applied in or to the outdoor environment”. The restriction to use of the substance only as a component in a veterinary medicine prevents use for these purposes. However, research and development use may still be possible in an exempt laboratory or by obtaining a containment approval for field trials for that purpose.</td></tr>
<tr><td>Deletion of control</td><td>The following controls are deleted:<br><br>
<table>
<tr><th>Control Code</th><th>Regulations</th><th>Description</th></tr>
<tr><td colspan="3">Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001</td></tr>
<tr><td>T8</td><td>28</td><td>Controls for vertebrate poisons</td></tr>
<tr><td>E4</td><td>50, 51</td><td>Controls relating to the protection of terrestrial vertebrates</td></tr>
</table>
</td><td>Since trichlorfon is not permitted to enter the environment, the Committee agrees that the controls which relate to the use of a hazardous substance that is discharged or laid in the environment should be deleted. The Committee considers the adverse effects identified for trichlorfon are less than the adverse effects which would usually be associated with substances given that hazard classification, and that the requirements of the test specified in s77(4)(a) are met.</td></tr>
</table>

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<tr><th>Substance / Approval #</th><th>Nature of amendment</th><th>Description of amendment</th><th>Comment and justification</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><th colspan="3">Hazardous Substances (Tracking) Regulations 2001</th></tr>
<tr><td>TR1</td><td>4(1), 5, 6</td><td>General tracking requirements</td></tr>
</table>
</td><td></td></tr>
<tr><td></td><td>Variation of control</td><td>
The following controls are varied:
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<tr><td colspan="3">Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001</td></tr>
<tr><td rowspan="2">T6, E7</td><td>9</td><td>Approved handler/security requirements for certain toxic substances</td></tr>
<tr><td colspan="2">Variation:<br>The control imposed by regulation 9 is deleted and replaced by the following control:<br>Trichlorfon must, if left unattended, be secured so that a person cannot gain access to the substance unless the person has a key or other device used for operating locks.</td></tr>
<tr><td rowspan="2">E1</td><td>32 - 45</td><td>Limiting exposure to ecotoxic substances through the setting of EELs</td></tr>
<tr><td colspan="2">Variation:<br>No EELs are set at this time, and the default values deleted.</td></tr>
</table>
</td><td>Variations to default controls T6 and E1 were made to the substance when it was originally approved. The Committee considers this variation to control T6 is more effective in its effect on the management, use and risks of the substance, than the existing controls and satisfies the requirements of the test in s77A(4)(a)..<br><br>The Committee notes that with regard to setting EELs for this substance (control E1), until formal policy has been developed on the implementation of section 77B, no EELs are set at this time.</td></tr>
<tr><td>Emulsion (oil in water) containing 500 g/litre trichlorfon<br><br>HSR000204</td><td>Decline of approval</td><td>Continued importation, manufacture or use of this substance is no longer approved.</td><td>In its reassessment application, the Agency identified risks to the environment from use as a plant protection product, which cannot be managed effectively. In light of this reassessment, the Committee considers that the continued use of trichlorfon for plant protection purposes cannot be justified given the level of benefits. As a result, the Committee considers that the continued</td></tr>
</table>

<table>
<tr><th>Substance / Approval #</th><th>Nature of amendment</th><th>Description of amendment</th><th>Comment and justification</th></tr>
<tr><td>Emulsifiable concentrate (micro emulsion) containing 20 g/litre cypermethrin and 400 g/litre trichlorfon<br><br>HSR000205</td><td>Decline of approval</td><td>Continued importation, manufacture or use of this substance is no longer approved.</td><td>importation, manufacture or use of the following trichlorfon-containing substances should not be permitted and declines the continued approval of these substances.</td></tr>
<tr><td rowspan="2">Solid containing 950-990 g/kg trichlorfon<br>HSR001951</td><td>Deletion of control</td><td>The following controls are deleted:<br><br>
<table>
<tr><th>Control Code</th><th>Regulations</th><th>Description</th></tr>
<tr><td colspan="3">Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001</td></tr>
<tr><td>T3, E5</td><td>5(1)/(2), 6</td><td>Requirements for keeping records of use</td></tr>
<tr><td>T8</td><td>28</td><td>Controls for vertebrate poisons</td></tr>
<tr><td colspan="3">Hazardous Substances (Tracking) Regulations 2001</td></tr>
<tr><td>TR1</td><td>4(1), 5, 6</td><td>General tracking requirements</td></tr>
</table></td><td>The controls were deleted for the substance when it was originally approved. The Committee considers that, given the lifecycle of the substance, the adverse effects of the substance are less than the adverse effects which would usually be associated with substances given that hazard classification, and that the requirements of the test specified in s 77(4)(a) are met.</td></tr>
<tr><td>Variation of control</td><td>The following controls are varied:<br><br>
<table>
<tr><th>Control Code</th><th>Regulations</th><th>Description</th></tr>
<tr><td colspan="3">Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001</td></tr>
<tr><td rowspan="2">T6, E7</td><td>9</td><td>Approved handler/security requirements for certain toxic substances</td></tr>
<tr><td colspan="2">Variation:</td></tr>
</table></td><td>A number of variations to the default controls were made to the substance when it was originally approved. The Committee considers these variations are more effective regarding the effect on the management, use and risks of the substance, than the existing controls and satisfies the requirements of the test in s77A(4)(a).<br><br>The Committee notes that with regard to setting EELs for this substance (control E1), until formal policy has been developed on the implementation of section 77B, no EELs are set at this</td></tr>
</table>

<table>
<tr><th>Substance / Approval #</th><th>Nature of amendment</th><th colspan="3">Description of amendment</th><th>Comment and justification</th></tr>
<tr><td></td><td></td><td></td><td colspan="2">The control imposed by regulation 9 is deleted and replaced by the following control:<br><br>Trichlorfon must, if left unattended, be secured so that a person cannot gain access to the substance unless the person has a key or other device used for operating locks.</td><td>time.</td></tr>
<tr><td></td><td></td><td>T7</td><td>10</td><td>Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles</td><td></td></tr>
<tr><td></td><td></td><td></td><td colspan="2">Variation:<br><br>The control imposed on this substance by regulation 10(1)(b) is deleted and replaced by:<br><br>The package contains no more than 3kg of the substance.</td><td></td></tr>
<tr><td></td><td></td><td>E1</td><td>32 - 45</td><td>Limiting exposure to ecotoxic substances through the setting of EELs</td><td></td></tr>
<tr><td></td><td></td><td></td><td colspan="2">Variation:<br>No EELs are set at this time, and the default values deleted.</td><td></td></tr>
<tr><td></td><td></td><td>E6</td><td>7</td><td>Requirements for equipment used to handle substances</td><td></td></tr>
<tr><td></td><td></td><td></td><td colspan="2">(1) The controls imposed by regulation 7 do not apply when the substance is being dispensed or administered to an animal.<br><br>(2) Subclause (1), above, does not apply to</td><td></td></tr>
</table>

<table>
<tr><th>Substance / Approval #</th><th>Nature of amendment</th><th>Description of amendment</th><th>Comment and justification</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td></td><td colspan="2">a substance that is—<br><br>(a) a powder, granule or other finely divided material; or<br><br>(b) dissolved prior to administration to an animal.</td></tr>
<tr><td colspan="3">Hazardous Substances (Identification) Regulations 2001</td></tr>
<tr><td rowspan="2">I16</td><td>25</td><td>Secondary identifiers for toxic substances</td></tr>
<tr><td colspan="2">Variation:<br><br>(1) The controls imposed by this regulation apply to this substance as if the substance were not a class 6.4 or class 6.5 hazardous substance.<br><br>(2) Subclause (1), above, does not apply to a substance that is—<br><br>(a) a powder, granule or other finely divided material; or<br><br>(b) dissolved prior to administration to an animal.</td></tr>
</table>
</td><td></td></tr>
<tr><td></td><td>Variation of control</td><td>Control T5 is varied to prescribe the minimum level of PPE to be worn during use of the substance:<br><br>The following control is added to the controls imposed by regulation 8:<br><br>(6) A person mixing and loading the substance, administering the substance as a drench or food additive, or entering a building where the substance has been applied to the surfaces and then dried, must wear chemical resistant gloves.</td><td>The Committee notes the Agency’s human health exposure assessment and the identified risks to human health. The Committee is satisfied that, by prescribing the use of specific PPE during the lifecycle of the substance, the controls will be more effective in terms of management, use and risks of the substance, than the current controls and thus the requirements of the test in section 77A(4)(a) are met.</td></tr>
</table>

| Substance / Approval # | Nature of amendment | Description of amendment | Comment and justification |
|---|---|---|---|
| | | (7) A person spraying the substance in an empty poultry house, or entering a building where the substance has been applied to the surfaces but not yet dried, must wear:<br>(a) coveralls over long-sleeved shirt, long-legged trousers and socks; and<br>(b) protective eyewear; and<br>(c) chemical resistant:<br>(i) headgear with visor for overhead exposures; and<br>(ii) gloves; and<br>(iii) footwear. | |
| | Additional control | **1. Prohibition on use of the substance**<br>No person may use this substance for any purpose other than—<br>(a) as an oral drench for sheep or pigs; or<br>(b) as an animal feed additive for pigs; or<br>(c) as a dilute surface spray for treatment of poultry houses without animals or birds present. | The Agency's assessment identified exposure risks to human health through use of the substance, but identified technical uncertainty regarding the level of exposure that may arise when the substance was spray applied to pigs or poultry.<br>The Committee considers that a restriction prohibiting use of the substance by spray application onto animals will be more effective in terms of management, use and risks of the substance, than the current controls and thus the requirements of the test in section 77A(4)(a) are met. |
| | Additional control | **2. Labelling requirements**<br>The following new risk reduction measures must be included on the product label:<br>(a) the requirements for protective clothing and equipment | The Committee is satisfied that requiring the new risk reduction measures to be identified will aid compliance and be more effective in terms of management, use and risks of the substance, than the current controls and thus the requirements of |

| Substance / Approval # | Nature of amendment | Description of amendment | Comment and justification |
|---|---|---|---|
| | | specified in the variation to reg 8 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 as set out in T5 above; and<br><br>(b) the prohibition on use of the substance set out in additional control 1 above. | the test in section 77A(4)(a) are met. |

# 13 Comparison of risks, cost and benefits

13.1.1 The Committee is required under the Act, to consider whether or not the positive effects (benefits) of using trichlorfon or trichlorfon-containing substances outweigh the adverse 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.

*Level of adverse effects*

13.1.2 The Committee considers that the adverse effects for the following substances are **negligible**, provided the additional controls are in place:

- **trichlorfon (Approval Number HSR002885);**
- **solid containing 950-990 g/kg trichlorfon (Approval Number HSR001951)**.

13.1.3 The Committee considers that the adverse effects for the following substances are significant and **non-negligible**, and that there are no practical measures that may reduce the level of adverse effects arising from use of the substances:

- **emulsion (oil in water) containing 500 g/litre trichlorfon (Approval Number HSR000204);**
- **emulsifiable concentrate (micro emulsion) containing 20 g/litre cypermethrin and 400 g/litre trichlorfon (Approval Number HSR000205).**

*Level of benefits*

13.1.4 The Committee notes the assessment of benefits contained in the Agency's reassessment application, which indicated that use of trichlorfon-containing substances provides a **negligible** level of benefit for all of the approved trichlorfon-containing substances.

*Likely effects of the substances being unavailable*

13.1.5 The Committee notes that alternative substances have been identified for all of the use scenarios, except for red-mite treatment on poultry. If the substances were to become unavailable, then users would become reliant on alternative substances, leading to a reduction in consumer choice.

*Conclusion*

13.1.6 Upon reviewing all the information contained in the application and received from submitters, the Committee accepts the Agency's evaluation that:

(a) with the additional controls in place, the availability and use of **trichlorfon (Approval Number HSR002885)** poses **negligible** adverse effects if its use is restricted to use as a component in veterinary medicines, and provides sufficient benefit to allow its continued importation, manufacture or use; and

(b) the benefits do not outweigh the adverse effects for use of trichlorfon-containing substances for plant protection purposes (i.e. **emulsion (oil in water) containing 500 g/litre trichlorfon (Approval Number HSR000204)** and **emulsifiable concentrate (micro emulsion) containing 20 g/litre cypermethrin and 400 g/litre trichlorfon (Approval Number HSR000205)**); and

(c) with the additional controls in place, for uses of trichlorfon-containing substances that pose **negligible** adverse effects as veterinary medicines, the availability of **solid containing 950-990 g/kg trichlorfon (Approval number HSR001951)** will provide sufficient benefit to allow its continued importation, manufacture or use.

# 14 Decision

14.1.1 Pursuant to sections 63 and 29, the Committee has considered this application to reassess trichlorfon and formulated substances containing trichlorfon.

**The Committee determines that:**

14.1.2 Based on consideration and analysis of the information provided on the possible effects of trichlorfon and trichlorfon-containing substances, in accordance with the Act and the Methodology, and taking into account the application of current controls (as varied) and the additional controls, the Committee is satisfied that, for the reasons set out in this decision—

- with additional controls applied, the positive effects (benefits) of **trichlorfon (Approval Number HSR002885)** outweigh the adverse effects (risks and costs) associated its import and use;
- with additional controls applied, the positive effects (benefits) of **solid containing 950-990 g/kg trichlorfon (Approval Number HSR001951)** outweigh the adverse effects (risks and costs) associated with its import and use;
- the adverse effects (risks and costs) of **emulsion (oil in water) containing 500 g/litre trichlorfon (Approval Number HSR000204)** outweigh the positive effects (benefits) associated with its import and use;
- the adverse effects (risks and costs) of **emulsifiable concentrate (micro emulsion) containing 20 g/litre cypermethrin and 400 g/litre trichlorfon (Approval Number HSR000205)** outweigh the positive effects (benefits) associated with its import and use.

14.1.3 Accordingly, continued importation, manufacture, use or disposal is not permitted under the approvals for—

- **emulsion (oil in water) containing 500 g/litre trichlorfon (Approval Number HSR000204)**; and
- **emulsifiable concentrate (micro emulsion) containing 20 g/litre cypermethrin and 400 g/litre trichlorfon (Approval Number HSR000205)**.

14.1.4 Approvals for **trichlorfon (Approval Number HSR002885)** and **solid containing 950-990 g/kg trichlorfon (Approval Number HSR001951)** are retained, with additional restrictions applied, and have the following hazard classifications:

| Hazard Class/Subclass | Trichlorfon (Approval # HSR002885) | Solid containing 950-990 g/kg trichlorfon (Approval # HSR001951) |
|---|---|---|
| Acute toxicity (oral) | 6.1C | 6.1C |
| Acute toxicity (dermal) | 6.1E | 6.1E |
| Acute toxicity (inhalation) | 6.1D | 6.1D |
| Eye irritancy/corrosion | 6.4A | 6.4A |
| Contact sensitisation | 6.5B | 6.5B |
| Mutagenicity | 6.6B | 6.6B |
| Carcinogenicity | 6.7B | 6.7B |
| Target organ systemic toxicity | 6.9A | 6.9A |
| Aquatic ecotoxicity | 9.1A | 9.1A |
| Soil ecotoxicity | 9.2B | 9.2B |
| Terrestrial vertebrate ecotoxicity | 9.3A | 9.3A |
| Terrestrial invertebrate ecotoxicity | 9.4B | 9.4B |

14.1.5 The applications for importation of **trichlorfon (Approval Number HSR002885)**, and **solid containing 950-990 g/kg trichlorfon (Approval Number HSR001951)** are approved, with the controls listed in **Appendix B**.

14.1.6 The amendments arising from this decision come into effect on 1 June 2011, to accommodate a three month phase-in period for the new approval conditions

14.1.7 The Committee requires the following substances to be disposed of (including through use of the substance) prior to 1 June 2011, at the owner's expense and in accordance with the current controls that applied to that substance (i.e. the controls that apply immediately prior to this approval taking effect):

- **emulsion (oil in water) containing 500 g/litre trichlorfon (Approval Number HSR000204)**; and
- **emulsifiable concentrate (micro emulsion) containing 20 g/litre cypermethrin and 400 g/litre trichlorfon (Approval Number HSR000205)**.

14.1.8 In accordance with clause 36(2)(b), the Committee records that, in reaching its decision, it has applied the balancing tests required under section 29 and clause 26 and has relied in particular on the following criteria in the Act and the Methodology:

clause 8 – information to be relevant and appropriate;

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 15 – regard to evidence in submissions;

clause 16 – take account of scientific basis for scientific evidence or uncertainty;

clause 21 – the decision accords with the requirements of the Act 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 and taking account of degree of uncertainty;

clause 26 – evident that risks and costs are outweighed by benefits;

clause 29 – determine the materiality and significance of any uncertainty;

clause 30 – take account of the need for caution where uncertainty is not resolved;

clause 32 – establish range of uncertainty;

clause 33 – the extent to which 'risk characteristics' exist;

clause 34 – the aggregation and comparison of risks, costs and benefits; and

clause 35 – the costs and benefits of varying the default controls and inviting the applicants to comment on cost-effective application of controls.

| | |
|---|---|
| Max Suckling | Date 18 February 2011 |
| Chair | |

# Appendix A: Decision path

## Context

This decision path describes the decision-making process for reassessments under section 63 of the Act. These reassessments are deemed to be applications are 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 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 Act, and 'clause' refers to clauses of the HSNO (Methodology) Order 1998 ("the Methodology").
The decision path has two parts –

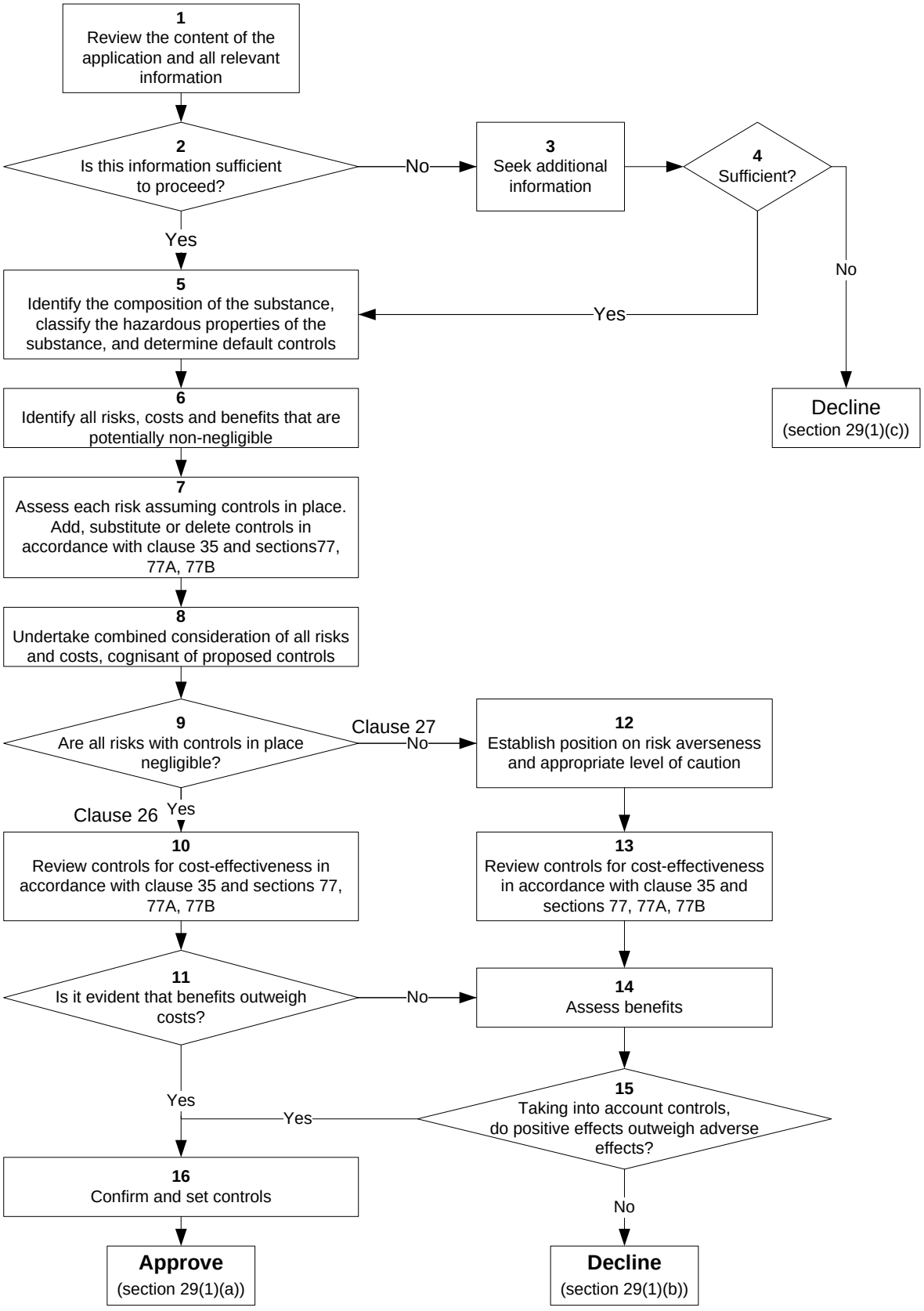
**Flowchart** (a logic diagram showing the process prescribed in the Methodology and the Act to be followed in making a decision), and
**Explanatory notes** (discussion of each step of the process).

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 more comprehensive description of each of the numbered items in the flowchart, and describe the processes that should be followed to achieve the described outcome.

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

## Figure A1: Flowchart for decision

Decision path for applications to reassess a hazardous substance, application made under section 63 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 A1: Explanatory notes

Item 1: **Review the content of the application and all relevant information**

Review the application, the update paper, 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

[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.

addressed together. If not, they will be addressed separately. Examples of costs 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 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

[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 significance 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".

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**

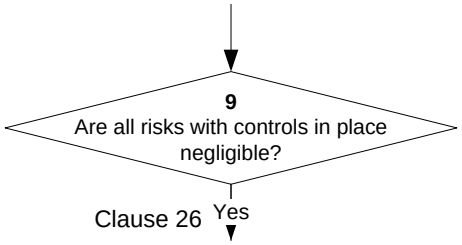
Once the risks and costs have been assessed individually, if appropriate consider all risks and costs together as a "basket" of risks/costs. This may involve combining groups of risks and costs as indicated in clause 34(a) of the Methodology where this is feasible and appropriate, or using other techniques 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] 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.

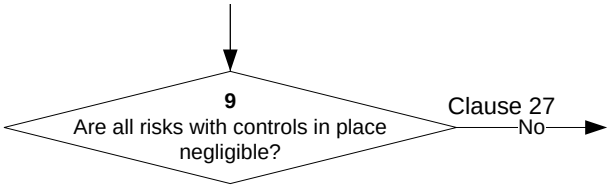
Consider whether there are any non-negligible external costs that are not associated with risks.

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).

[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:

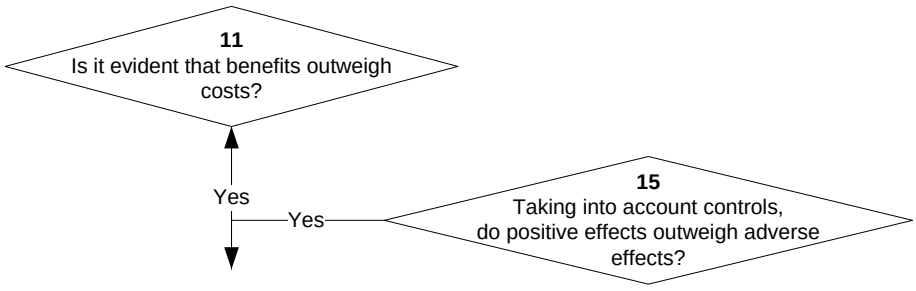
**Taking into account controls, do positive effects outweigh adverse effects?**

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 B: Controls

B1.1 Unless otherwise specified, the controls on the approvals that applied to **trichlorfon (Approval Number HSR002885)** and **solid containing 950-990 g/kg trichlorfon (HSR001951)** immediately before this decision continue in effect until 1 June 2011.

B1.2 The controls for trichlorfon set out in **Table B1** of this Appendix take effect from the date of this decision but need not be complied with until 1 June 2011.

B1.3 The controls for **solid containing 950-990 g/kg trichlorfon (Approval Number HSR001951)** set out in **Table B2** of this Appendix take effect from the date of this approval but need not be complied with until 1 June 2011.

B1.4 Until 1 June 2011, compliance with a control set out in **Table B1** or **Table B2** of this Appendix that, with or without modification, replaces or corresponds to a control for the substances referred to in paragraph B1.1 above, constitutes compliance with the control that it replaces or corresponds to.

B1.5 From the date of this decision a control imposed on an approval referred to in paragraph B1.1 need not be complied with if it will be deleted and not replaced as at 1 June 2011 by a control set out in **Table B1** or **Table B2** of this Appendix.

B1.6 The controls on the approvals that applied to **emulsion (oil in water) containing 500 g/litre trichlorfon (Approval Number HSR000204)** and **emulsifiable concentrate (micro emulsion) containing 20 g/litre cypermethrin and 400 g/litre trichlorfon (Approval Number HSR000205)** immediately before this decision continue in effect until 1 June 2011.

**Table B1. Amended controls for trichlorfon (HSR002885).**

**Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001**

| Code | Regulation | Description | Variation |
|---|---|---|---|
| T1 | Regs 11 – 27 | Limiting exposure to toxic substances through the setting of TELs | No ADE, PDE, TELs set at this time for this substance. |
| T2 | Regs 29, 30 | Controlling exposure in places of work through the setting of WESs. | No WES values are set for this substance at this time. |
| T3 | Regs 5(1), 6 | Requirements for keeping records of use | |
| T4 | Reg 7 | Requirements for equipment used to handle substances | |
| T5 | Reg 8 | Requirements for protective clothing and equipment | |
| T6 | Reg 9 | Approved handler/security requirements for certain toxic substances | The control imposed by regulation 9 is deleted and replaced by the following control: |

| | | | |
|---|---|---|---|
| | | | Trichlorfon must, if left unattended, be secured so that a person cannot gain access to the substance unless the person has a key or other device used for operating locks. |
| | *Explanation: You do not need to be an approved handler to use this substance but it must be kept secured when not being used.* | | |
| T7 | Reg 10 | Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles | |

**Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001**

| Code | Regulation | Description | Variation |
|---|---|---|---|
| E1 | Regs 32 – 45 | Limiting exposure to ecotoxic substances through the setting of EELs | No EELs are set at this time, and the default values deleted. |
| E2 | Regs 46 – 48 | Restrictions on use of substances in application areas | |
| E3 | Reg 49 | Controls relating to protection of terrestrial invertebrates eg beneficial insects | |
| E5 | Regs 5(2), 6 | Requirements for keeping records of use | |
| E6 | Reg 7 | Requirements for equipment used to handle substances | |
| E7 | Reg 9 | Approved handler/security requirements for certain ecotoxic substances | The control imposed by regulation 9 is deleted and replaced by the following control:<br><br>Trichlorfon must, if left unattended, be secured so that a person cannot gain access to the substance unless the person has a key or other device used for operating locks. |
| | *Explanation: You do not need to be an approved handler to use this substance but it must be kept secured when not being used.* | | |

**Hazardous Substances (Identification) Regulations 2001**

| Code | Regulation | Description | Variation |
|---|---|---|---|
| I1 | Regs 6, 7, 32 – 35, 36(1) – (7) | Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability | |
| I3 | Reg 9 | Priority identifiers for ecotoxic substances | |
| I8 | Reg 14 | Priority identifiers for toxic substances | |

| | | | |
|---|---|---|---|
| I9 | Reg 18 | Secondary identifiers for all hazardous substances | |
| I11 | Reg 20 | Secondary identifiers for ecotoxic substances | |
| I16 | Reg 25 | Secondary identifiers for toxic substances | |
| I17 | Reg 26 | Use of generic names | |
| I18 | Reg 27 | Requirements for using concentration ranges | |
| I19 | Regs 29 – 31 | Additional information requirements, including situations where substances are in multiple packaging | |
| I20 | Reg 36(8) | Durability of information for class 6.1 substances | |
| I21 | Regs 37 – 39, 47 – 50 | General documentation requirements | |
| I23 | Reg 41 | Specific documentation requirements for ecotoxic substances | |
| I28 | Reg 46 | Specific documentation requirements for toxic substances | |
| I29 | Regs 51, 52 | Signage requirements | |
| I30 | Reg 53 | Advertising corrosive and toxic substances | |

**Hazardous Substances (Packaging) Regulations 2001**

| Code | Regulation | Description | Variation |
|---|---|---|---|
| P1 | Regs 5, 6, 7(1), 8 | General packaging requirements | |
| P3 | Reg 9 | Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria | |
| P13 | Reg 19 | Packaging requirements for toxic substances | |
| P15 | Reg 21 | Packaging requirements for ecotoxic substances | |
| PG3 | Schedule 3 | Packaging requirements equivalent to UN Packing Group III | |

**Hazardous Substances (Disposal) Regulations 2001**

| Code | Regulation | Description | Variation |
|---|---|---|---|
| D4 | Reg 8 | Disposal requirements for toxic and corrosive substances | |

| | | | |
|---|---|---|---|
| D5 | Reg 9 | Disposal requirements for ecotoxic substances | |
| D6 | Reg 10 | Disposal requirements for packages | |
| D7 | Regs 11, 12 | Information requirements for manufacturers, importers and suppliers, and persons in charge | |
| D8 | Regs 13, 14 | Documentation requirements for manufacturers, importers and suppliers, and persons in charge | |

**Hazardous Substances (Emergency Management) Regulations 2001**

| Code | Regulation | Description | Variation |
|---|---|---|---|
| EM1 | Regs 6, 7, 9 – 11 | Level 1 information requirements for suppliers and persons in charge | |
| EM6 | Reg 8(e) | Information requirements for toxic substances | |
| EM7 | Reg 8(f) | Information requirements for ecotoxic substances | |
| EM8 | Regs 12 – 16, 18 – 20 | Level 2 information requirements for suppliers and persons in charge | |
| EM11 | Regs 25 – 34 | Level 3 emergency management requirements: duties of person in charge, emergency response plans | |
| EM13 | Reg 42 | Level 3 emergency management requirements: signage | |

**Hazardous Substances (Tank Wagon and Transportable Containers) Regulations 2004**

| Code | Regulation | Description | Variation |
|---|---|---|---|
| Tank Wagon | Regs 4 to 43 as applicable | Controls relating to tank wagons and transportable containers. | |

**Hazardous Substances (Personnel Qualifications) Regulations 2001**

| Code | Regulation | Description | Variation |
|---|---|---|---|
| AH 1 | Regs 4 – 6 | Approved Handler requirements (including test certificate and qualification requirements) | See control codes T6 and E7. |
| | *Explanation: You do not need to be an approved handler to use this substance but it must be kept secured when not being used.* | | |

**Additional controls**

| **Addition controls applied under section 77A** |
|---|
| **Prohibition on use of trichlorfon** |
| No person may use trichlorfon for any purpose other than as an ingredient or component in the manufacture of a |

| |
|---|
| veterinary medicine. |

**Table B2. Amended controls for solid containing 950-990 g/kg trichlorfon (HSR001951).**

**Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001**

| Code | Regulation | Description | Variation |
|---|---|---|---|
| T1 | Regs 11 – 27 | Limiting exposure to toxic substances through the setting of TELs | No tolerable exposure limit (TEL) is set for this substance at this time. |
| T2 | Regs 29, 30 | Controlling exposure in places of work through the setting of WESs. | |
| T4 | Reg 7 | Requirements for equipment used to handle substances | (1) The controls imposed by regulation 7 do not apply when the substance is being dispensed or administered to an animal.<br><br>(2) Subclause (1), above, does not apply to a substance that is—<br><br>(a) a powder, granule or other finely divided material; or<br><br>(b) dissolved prior to administration to an animal. |
| T5 | Reg 8 | Requirements for protective clothing and equipment | The following control is added to the controls imposed by regulation 8:<br><br>(6) A person mixing and loading the substance, administering the substance as a drench or food additive, or entering a building where the substance has been applied to the surfaces and then dried, must wear chemical resistant gloves.<br><br>(7) A person spraying the substance in an empty poultry house, or entering a building where the substance has been applied to the surfaces but not yet dried, must wear:<br><br>(a) coveralls over long-sleeved shirt, long-legged trousers and socks; and<br><br>(b) protective eyewear; and<br><br>(c) chemical resistant:<br><br>(i) headgear with visor for overhead exposures; and<br><br>(ii) gloves; and<br><br>(iii) footwear. |

| | | | |
|---|---|---|---|
| T6 | Reg 9 | Approved handler/security requirements for certain toxic substances | The control imposed by regulation 9 is deleted and replaced by the following control:<br><br>Trichlorfon must, if left unattended, be secured so that a person cannot gain access to the substance unless the person has a key or other device used for operating locks. |
| | *Explanation: You do not need to be an approved handler to use this substance but it must be kept secured when not being used.* | | |
| T7 | Reg 10 | Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles | The control imposed on this substance by regulation 10(1)(b) is deleted and replaced by:<br><br>The package contains no more than 3kg of the substance. |

**Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001**

| Code | Regulation | Description | Variation |
|---|---|---|---|
| E1 | Regs 32 – 45 | Limiting exposure to ecotoxic substances through the setting of EELs | No EELs are set at this time, and the default values deleted. |
| E6 | Reg 7 | Requirements for equipment used to handle substances | (1) The controls imposed by regulation 7 do not apply when the substance is being dispensed or administered to an animal.<br><br>(2) Subclause (1), above, does not apply to a substance that is—<br><br>(a) a powder, granule or other finely divided material; or<br><br>(b) dissolved prior to administration to an animal. |
| E7 | Reg 9 | Approved handler/security requirements for certain ecotoxic substances | The control imposed by regulation 9 is deleted and replaced by the following control:<br><br>Trichlorfon must, if left unattended, be secured so that a person cannot gain access to the substance unless the person has a key or other device used for operating locks. |
| | *Explanation: You do not need to be an approved handler to use this substance but it must be kept secured when not being used.* | | |

**Hazardous Substances (Identification) Regulations 2001**

| Code | Regulation | Description | Variation |
|---|---|---|---|
| I1 | Regs 6, 7, 32 – 35, 36(1) – (7) | Identification requirements, duties of persons in charge, accessibility, | |

| | | | |
|---|---|---|---|
| | | comprehensibility, clarity and durability | |
| I3 | Reg 9 | Priority identifiers for ecotoxic substances | |
| I8 | Reg 14 | Priority identifiers for toxic substances | |
| I9 | Reg 18 | Secondary identifiers for all hazardous substances | |
| I11 | Reg 20 | Secondary identifiers for ecotoxic substances | |
| I16 | Reg 25 | Secondary identifiers for toxic substances | (1) The controls imposed by this regulation apply to this substance as if the substance were not a class 6.4 or class 6.5 hazardous substance.<br><br>(2) Subclause (1), above, does not apply to a substance that is—<br><br>(a) a powder, granule or other finely divided material; or<br><br>(b) dissolved prior to administration to an animal. |
| I17 | Reg 26 | Use of generic names | |
| I18 | Reg 27 | Requirements for using concentration ranges | |
| I19 | Regs 29 – 31 | Additional information requirements, including situations where substances are in multiple packaging | |
| I20 | Reg 36(8) | Durability of information for class 6.1 substances | |
| I21 | Regs 37 – 39, 47 – 50 | General documentation requirements | |
| I23 | Reg 41 | Specific documentation requirements for ecotoxic substances | |
| I28 | Reg 46 | Specific documentation requirements for toxic substances | |
| I29 | Regs 51, 52 | Signage requirements | |
| I30 | Reg 53 | Advertising corrosive and toxic substances | |

**Hazardous Substances (Packaging) Regulations 2001**

| Code | Regulation | Description | Variation |
|---|---|---|---|

| | | | |
|---|---|---|---|
| P1 | Regs 5, 6, 7(1), 8 | General packaging requirements | |
| P3 | Reg 9 | Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria | |
| P13 | Reg 19 | Packaging requirements for toxic substances | |
| P15 | Reg 21 | Packaging requirements for ecotoxic substances | |

**Hazardous Substances (Packaging) Regulations 2001**

| Code | Regulation | Description | Variation |
|---|---|---|---|
| PG3 | Schedule 3 | Packaging requirements equivalent to UN Packing Group III | |

**Hazardous Substances (Disposal) Regulations 2001**

| Code | Regulation | Description | Variation |
|---|---|---|---|
| D4 | Reg 8 | Disposal requirements for toxic and corrosive substances | |
| D5 | Reg 9 | Disposal requirements for ecotoxic substances | |
| D6 | Reg 10 | Disposal requirements for packages | |
| D7 | Regs 11, 12 | Information requirements for manufacturers, importers and suppliers, and persons in charge | |
| D8 | Regs 13, 14 | Documentation requirements for manufacturers, importers and suppliers, and persons in charge | |

**Hazardous Substances (Emergency Management) Regulations 2001**

| Code | Regulation | Description | Variation |
|---|---|---|---|
| EM1 | Regs 6, 7, 9 – 11 | Level 1 information requirements for suppliers and persons in charge | |
| EM6 | Reg 8(e) | Information requirements for toxic substances | |
| EM7 | Reg 8(f) | Information requirements for ecotoxic substances | |
| EM8 | Regs 12 – 16, 18 – 20 | Level 2 information requirements for suppliers and persons in charge | |
| EM11 | Regs 25 – 34 | Level 3 emergency management requirements: duties of person in charge, emergency response plans | |

| | | | |
|---|---|---|---|
| EM13 | Reg 42 | Level 3 emergency management requirements: signage | |

**Hazardous Substances (Personnel Qualifications) Regulations 2001**

| Code | Regulation | Description | Variation |
|---|---|---|---|
| AH 1 | Regs 4 – 6 | Approved Handler requirements (including test certificate and qualification requirements) | See control codes T6 and E7. |
| | *Explanation: You do not need to be an approved handler to use this substance but it must be kept secured when not being used.* | | |

**Additional Controls**

| **Addition controls applied under section 77A** |
|---|
| **1. Prohibition on use of the substance**<br>No person may use this substance for any purpose other than—<br>(a) as an oral drench for sheep or pigs; or<br>(b) as an animal feed additive for pigs; or<br>(c) as a dilute surface spray for treatment of poultry houses without animals or birds present. |
| **2. Labelling requirements**<br>The following risk reduction measures must be included on the product label:<br>(a) the requirements for protective clothing and equipment specified in the variation to reg 8 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 as set out in T5 above; and<br>(b) the prohibition on use of the substance set out in **additional control 1** above. |