ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

22 March 2010

Application Code	ERMA200066
Application Type	To import or manufacture for release any hazardous substance under Section 28 of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Applicant	Renovo Technologies Limited
Date Application Received	26 August 2009
Submission Period	09 September 2009 – 21 October 2009
Consideration Date	05 February 2010
Considered by	A Committee of the Authority ('the Committee")
Purpose of the Application	Modified reassessment for use of chlorpropham.

1 Summary of decision

1.1 The application for modified reassessment of chlorpropham is **approved with controls.**

1.2 In making this decision the Committee has applied the relevant sections of the Act and clauses of the Methodology as detailed in the decision path attached to this decision as Appendix 1.

1.3 The substance is identified in the ERMA New Zealand Hazardous Substances Register as:

chlorpropham

2 Application process

2.1 The application was formally received on 26 August 2009 and was publicly notified on 09 September 2009 with submissions closing on 21 October 2009.

- No comments or submissions were received.

2.2 The Agency prepared a consideration paper to aid the Committee in its decision making process. The consideration paper consists of the Agency's review of the application and available data regarding the substance and/or its constituent components. In the consideration paper, the Agency proposed that a number of modifications be made to the existing suite of controls that already apply to the

chlorpropham approval. These controls are intended to manage the potential risks the substance may pose to the environment, human health, Māori, society and community and to the market economy when it is used as proposed by the applicant.

2.3 The Department of Labour, the New Zealand Food Safety Authority (Agricultural Compounds and Veterinary Medicines (ACVM) Group) and the applicant were given the opportunity to comment on the consideration paper and the controls proposed therein.

2.4 The following members of the Authority considered the application: Helen Atkins (Chair) and Shaun Ogilvie.

2.5 The information available to the Committee comprised:

- the application; and
- the consideration paper.

3 Consideration

Purpose of the application

3.1 The applicant has requested that the Authority modify the existing approval for chlorpropham to allow its use as a pesticide. In particular the applicant seeks approval to use the substance as a growth inhibitor to suppress sprout formation on potatoes in storage.

Hazard classification

3.2 Chlorpropham (CAS number 101-21-3) was transferred to the HSNO regime by way of the Hazardous Substances (Chemicals) Transfer Notice 2006 and classified as follows:

Hazardous Property	Classification
Acute Toxicity (Oral)	6.1E
Eye irritant	6.4A
Target Organ Toxicity	6.9B
Aquatic Ecotoxicity	9.1A
Soil Ecotoxicity	9.2A

Default controls

3.3 In the consideration paper, the Agency proposed several changes to the default controls that applied to the existing approval for chlorpropham. A full list of the controls and variations that were proposed by the Agency for chlorpropham is given in Appendix 4 of the consideration paper.

Identification of the potentially non-negligible risks, costs and benefits of the substance

3.4 The Agency has identified potentially significant, and therefore non-negligible, risks, costs and benefits associated with a change in the use of chlorpropham. This information is detailed in the consideration paper.

3.5 The Agency's evaluation concluded that, taking into account the controls that would apply, the use of the substance in the manner proposed by the applicant would present ***negligible*** risks.

3.6 The Agency noted that there would be potentially significant benefits associated with the change in use of chlorpropham, as follows:

- existing formulations containing chlorpropham for use as sprout growth regulators are flammable liquid formulations. Use of solid briquettes for the same purpose removes the risks that arise through use of flammable liquids;
- briquettes of solid chlorpropham are easier to handle, and the solid substance is easier to contain in the event of spillage, reducing the extent of exposure that may result; and
- solid briquettes contain > 98% chlorpropham, compared with 50% chlorpropham in the liquid formulations. The solid substance requires less packaging when compared to the liquid formulations, and also reductions in transportation and storage costs for comparable quantities of chlorpropham.

3.7 Taking into account the Agency's assessment of the potential risks and costs associated with a change in the use of chlorpropham as proposed by the applicant, the Committee considers that, with controls in place:

- the risks to human health and safety arising from the effects associated with the proposed use of chlorpropham are ***negligible***;
- the risks to the environment arising from the effects associated with the proposed use of chlorpropham are ***negligible***;
- significant adverse impacts on the social or economic environment with the controlled use of chlorpropham are not anticipated;
- it is unlikely that the use of chlorpropham in the manner intended by the applicant could have a significant impact on Māori culture or traditional relationships with ancestral lands, water, sites, wāhi tapu, valued flora and fauna or other taonga;
- there is no evidence to suggest that the controlled use of chlorpropham will breach the principles of the Treaty of Waitangi.

3.8 A number of variations to the default controls for chlorpropham were proposed in the consideration paper. These variations and the setting of exposure limits and application rates are discussed below.

Setting of exposure limits and application rates

3.9 Control **T1** relates to the requirement to limit public exposure to toxic substances by the setting of Tolerable Exposure Limits (TELs). When used as a pesticide, the Committee considers that the requirements for the setting of an ADE, PDE and TEL values. However, ADE, PDE and TEL values have not been set pending a review of setting such values under section 77B.

3.10 Control **T2** relates to the requirement to limit worker exposure to toxic substances by the setting of Workplace Exposure Standards (WESs). No WES value is set for chlorpropham at this time.

3.11 Control **E1** relates to the requirements to limit exposure of non-target organisms in the environment through the setting of Environmental Exposure Limits (EELs). The existing approval removed this control. However, the Committee consider that, this control should apply for use of chlorpropham as a pesticide. However, the Committee is reviewing the setting of EELs. As this review has not been completed, no EEL is being set for chlorpropham and the default values are deleted.

3.12 Control **E2** relates to the requirement to set an application rate for a class 9 substance that is to be sprayed on an area of land (or air or water) and for which an EEL has been set. As no EEL has been set for chlorpropham, the Committee is not able to set maximum application rates under this regulation. However, the Committee considers it appropriate to set a maximum application rate under section 77A.

Proposed additions and modifications to controls

3.13 The Committee notes that the existing use restriction controls for chlorpropham limits how the substance may be used (Schedule 3 of the Hazardous Substances (Chemicals) Transfer Notice (New Zealand Gazette Issue No. 72, 28 June 2006)):

> *(1) No person may use chlorpropham for any purpose other than—*
>
> *(a) for research and development; or*
>
> *(b) as an ingredient or component in the manufacture of another substance or product.*
>
> *(2) Despite subclause (1)(a), research and development using chlorpropham does not include investigation or experimentation in which the substance is discharged, laid or applied in or to the outdoor environment.*

3.14 In order to allow chlorpropham to be used as a growth regulator an additional control should be applied to allow a specific exclusion from this control to permit use as a sprout growth regulator. The Committee considers that the following control should be added to allow use of chlorpropham as a growth regulator (sprout inhibitor) for use on potatoes. The Committee notes that use of the substance may pose a risk to human health if it is used in a manner other than as proposed by the applicant. The Committee also considers that, the atmosphere in the treated warehouse contains chlorpropham it may pose a risk

to a human health. Accordingly, the Committee considers that the application of controls addressing these risks will be more effective than the specified (default) controls in terms of their effect on the management, use and risks of the substance (section 77A(4)(a)).

3.15 Consequently, the following additional controls are proposed to be added after the existing use restriction controls for chlorpropham to restrict the level of risk to human health:

> *(3) Despite subclause (1), chlorpropham may be applied in storage warehouses for use as a sprout inhibitor on potatoes, provided that —*
>
> *(a) application is made using a fogging machine, externally located to the treatment warehouse; and*
>
> *(b) the maximum application rates of chlorpropham are:*
>
> *0.0145 kg / 1,000 kg potatoes in bulk stores;*
>
> *0.0215 kg / 1,000 kg potatoes in box stores.*
>
> *(c) no person without PPE shall enter treated areas until after 2 hours of mechanical ventilation or 4 hours of passive ventilation. If visible aerosol remains after these periods, do not allow a person without PPE to enter until aerosol has settled.*

3.16 The Committee considers that the impurity, chloroaniline, may be present in chlorpropham up to a maximum concentration of 250 mg / kg (0.025%). Accordingly, the Committee considers that the following shall be added as an additional control (section 77A(4)(a)) and that the following subclause should be added immediately after the existing specification requirements for chlorpropham:

> *(5) The maximum concentration of chloroaniline in chlorpropham shall be 250 mg/kg.*

3.17 The Committee notes that there are no approved handler requirements applied to the existing approval for chlorpropham as a single component. However, approved handler requirements are in place for formulated substances containing chlorpropham used as sprout inhibitors, but no use restrictions are specified. The Committee considers that the restricted use pattern and physical form of the substance, and implementation of the other specified additional controls, will ensure that the risks are sufficiently managed without requiring approved handlers.

Summary of controls

3.18 The Committee has taken into consideration the controls imposed on approvals given to other pesticides used as sprout inhibitors that contain chlorpropham under Part 5 of the Act, as well as those transferred to the Act under the Hazardous Substances (Pesticides) Transfer Notice 2004 (as amended) and under the Hazardous Substances (Chemicals) Transfer Notice 2006 and considers that the controls listed in Appendix 4 should apply to the substance.

3.19 The Committee notes that the Summary of Approvals of Substances transferred under the Hazardous Substances (Chemicals) Transfer Notice 2006 should be

updated to reflect the change in controls applicable to chlorpropham. The following additions (or equivalent) shall be made to Schedule 3:

- The following subclause shall be added immediately after clause 1(5) of that schedule:

(6) Despite subclause (1), chlorpropham may be applied in storage warehouses for use as a sprout inhibitor on potatoes, provided that —

(a) application is made using a fogging machine, externally located to the treatment warehouse; and

(b) the maximum application rates of chlorpropham are:

0.0145 kg / 1,000 kg potatoes in bulk stores;

0.0215 kg / 1,000 kg potatoes in box stores.

(c) no person without PPE shall enter treated areas until after 2 hours of mechanical ventilation or 4 hours of passive ventilation. If visible aerosol remains after these periods, do not allow a person without PPE to enter until aerosol has settled.

3.20 The following subclause shall be added immediately after clause 2(4) of that schedule:

(5) The maximum concentration of chloroaniline in chlorpropham shall be 250 mg/kg.

4 Overall evaluation of risks and costs

4.1 On the basis of the assessment of risks and costs and taking into account the controls imposed, including the additional controls, the Committee considers that the change in use that has been proposed by the applicant for the substance chlorpropham, poses negligible risks and costs.

5 Review of controls for cost-effectiveness

5.1 The Committee considers that the proposed controls are the most cost-effective means of managing the identified potential risks and costs associated with this application.

5.2 The applicant was given an opportunity to comment on the proposed controls as set out in the consideration paper. The applicant indicated they had no issues with the proposed controls.

6 Comparison of risks, cost and benefits

6.1 As the Committee considers that the risks associated with the change in use of chlorpropham as proposed by the applicant are negligible with controls in place. Noting that no costs have been identified, the Committee is satisfied that the potential benefits associated with the substance outweigh the risks and costs.

7 Recommendations

7.1 The Committee recommends that, should inappropriate or accidental use, transport or disposal of chlorpropham result in the contamination of waterways, the appropriate authorities, including the relevant iwi authorities in the region, should be notified. This action should include advising them of the contamination and the measures taken in response.

7.2 The Committee considers that establishing a re-entry interval restriction for use of chlorpropham in the fogging of potato storage warehouses is equally appropriate for existing chlorpropham-containing formulations and should be included in the controls that apply to those approvals.

7.3 The Committee considers that the modified reassessment meets the requirements of best international practices and standards for the safe management of hazardous substances.

7.4 The Committee considers that the application for the modified reassessment meets the requirements of section 63A(6) and, therefore, may be approved in accordance with clause 26.

7.5 The Committee considers that the controls listed in Appendix 2 of this document shall apply to chlorpropham.

8 Environmental user charges

8.1 The Committee considers that the application of controls to chlorpropham will provide an effective means of managing risks associated with this substance. At this time no consideration has been given to whether or not environmental charges should be applied to this substance as an alternative or additional means of achieving effective risk management.

9 Confirmation and setting of controls

9.1 The controls listed in Appendix 2 will apply to chlorpropham.

10 Decision

10.1 The Committee determines that:

10.1.1 Chlorpropham has the following hazard classifications:

Hazardous Property	Classification
Acute Toxicity (Oral)	6.1E
Eye irritant	6.4A
Target Organ Toxicity	6.9B
Aquatic Ecotoxicity	9.1A
Soil Ecotoxicity	9.2A

10.1.2 The benefits of using chlorpropham as a sprout growth regulator outweigh the risks and costs.

10.1.3 The application for modified reassessment of the hazardous substance, chlorpropham, is thus **approved** with controls as listed in Appendix 2.

Ms Helen Atkins Date: 22 March 2010

Chair

ERMA New Zealand Approval Code: HSR002826

Appendix 1: Decision Path

Context

This decision path describes the decision-making process for applications to **modify an approval to import or manufacture a hazardous substance** under section 63A of the HSNO 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.

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

Figure 1 Flowchart

Decision path for modified reassessment for amendments to hazardous substance approvals: application made and determined under section 63A.

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

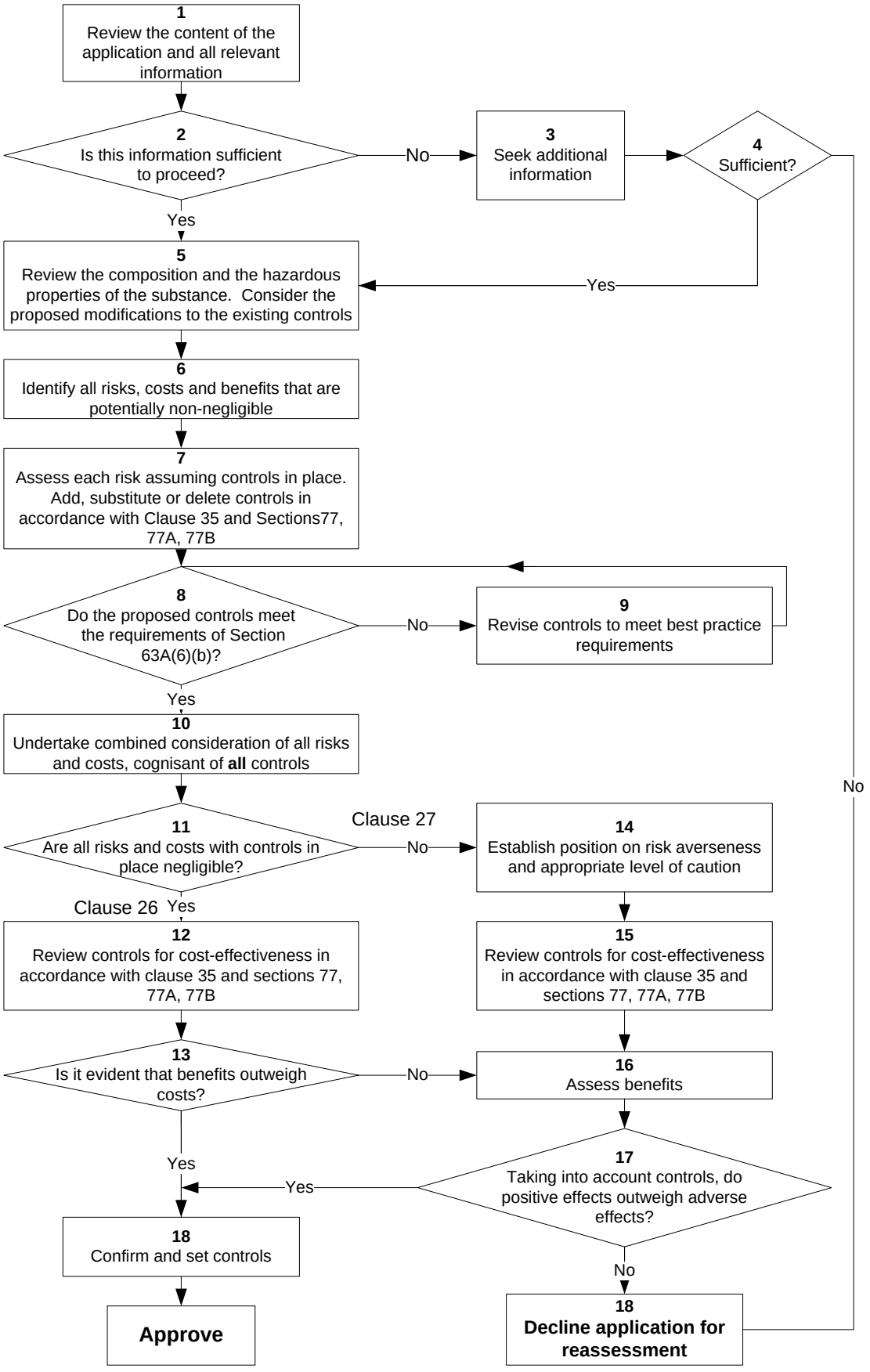


Figure 1 EXPLANATORY NOTES

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.

While section 63A is not mentioned in section 53 (public notification), sections 63A(4) and (5) provide discretion for the Authority to consider public notification (cf section 53(2)) and guidance re consultation where an application is not publicly notified.

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.

Item 3: (if 'no') Seek additional information
If there is not sufficient information then additional information may need to be sought under section 52 or 58 of the Act.

If the applicant is not able to provide sufficient information for consideration then the application is not approved. In these circumstances the Authority may choose to decline the application, or the application may lapse.

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 for reassessment must be declined (see item 18).

Item 5: (if 'yes' from item 2 or from item 4) Review the composition and the hazardous properties of the substance, and the proposed modifications to the existing controls
Review the composition of the substance, its hazardous properties, and the existing suite of controls on the substance. The level of detail for this review will depend on the nature of the application for modified reassessment. In most cases a detailed review will not be required.

Consider the proposed modifications to the existing controls.

Item 6: Identify all risks, costs and benefits that are potentially non-negligible[1]
The modified reassessment process concentrates on a specific aspect of the

[1] 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.

approval (section 63A(1)(a)). All risks, costs and benefits that are potentially non-negligible need to be identified. However, emphasis should be placed on effects that are expected to change as a result of the proposed changes to controls.

Costs and benefits are defined in the Methodology as the value of particular effects. However, in most cases these 'values' are not certain and have a likelihood attached to them. Thus costs and risks are generally synonymous and may be addressed together. Examples of costs that cannot be considered as risks are one-off direct financial costs incurred by applicants, that cannot be considered as 'sunk' costs (see footnote 1). Where such costs arise they will considered in the same way as risks, but their likelihood of occurrence will be more certain.

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[2]. 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[3], 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.

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

[3] 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.

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 its 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 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[4].

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 12 and 15.

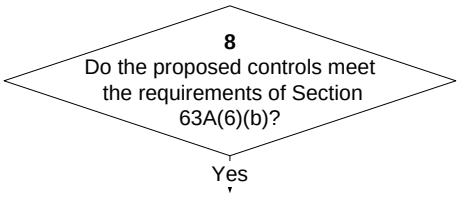
If changes are made to the controls at this stage then the approach to uncertainty and the approach to risk must be revisited.

Item 8: Do the proposed controls meet the requirements of Section 63A(6)(b)?
Consider whether the proposed controls meet best international practices and standards for the safe management of hazardous substances. This includes the full suite of proposed controls including existing controls and modified controls.

Item 9: (if 'no' from item 8) Revise controls to meet best practice requirements
If the controls do not meet the best international practice criteria, then modify the controls so that they do meet them.

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

Item 10:



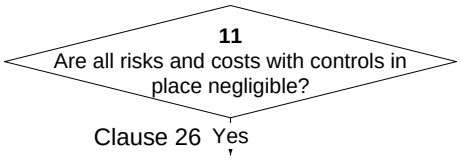
(if 'yes' from item 8) Undertake combined consideration of all risks and costs, cognisant of proposed controls

Once the risks and costs have been assessed individually consider all risks and costs together as a 'basket' of risks/costs. If it is feasible and/or appropriate, this may involve combining groups of risks and costs as for Clause 34 of the Methodology. The purpose of this step is to consider synergistic effects and determine whether these may change the level of individual risks.

Item 11: **Are all risks and costs with controls in place negligible?**

Looking at individual risks in the context of the 'basket' of risks, consider whether any of the residual risks (costs) are negligible.

Item 12:



(if 'yes' from item 11) 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 cost-effectiveness of the proposed individual controls and exposure limits. 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 13: **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.

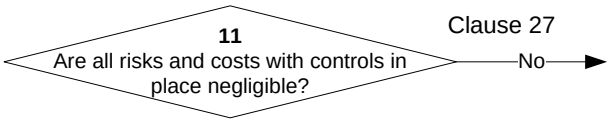
Consider whether there are any non-negligible external costs that are not associated with risks.

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[5]. 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 16).

Item 14:



(if 'no' from item 10) 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 15: **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 10, 13, 14 and 15).

Consider (a) whether any of the non-negligible risks can be reduced by varying the controls in accordance with section 77 and 77A of the Act, and (b) the cost-effectiveness of the controls. Where relevant and appropriate, add, substitute or delete controls whilst taking into account the view of the applicant, and making sure that the benefits of doing so outweigh the costs. As for item 6, If the substance has toxic or ecotoxic properties, consider exposure limits under section 77B.

Item 16: **(if 'no' from item 13, or in sequence from item 15) 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 its 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

[5]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'.

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[6]. 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 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 17: **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 (9), 12 and/or 15.

Where this item is taken in sequence from items 14, 15 and 16 (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 11, 12 and 13 (i.e. risks are negligible, and there are external or public costs) it constitutes a decision made under clause 26 of the Methodology.

Item 18: **(if 'no' from item 4 or item 17) Decline application for reassessment**

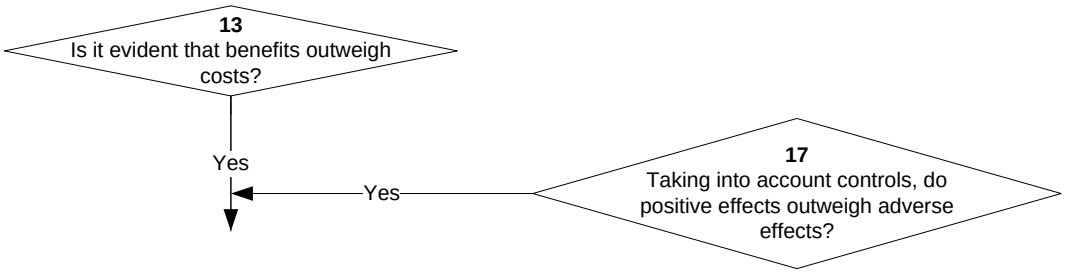
(from item 4) The Act is silent on the situation if there is insufficient information to consider the application. However, sections 55-61 (section 63A(3)) are deemed to hold, therefore the Authority concludes that the application for reassessment may be declined if there is insufficient information.

(from item 17) The Authority may decline the application under section 63A(6) after taking into account the effects of the substance and best international practices and standards.

Section 63A(2)(b) notes that this modified reassessment process cannot result in an approval to import or manufacture the substance being revoked. Therefore, if the process results in a 'decline' decision, then the result is that the modified reassessment of the substance is not approved, and the existing controls remain in force.

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

Item 19:



(if 'yes' from items 13 or 17) Confirm and set controls

Controls have been considered at the earlier stages of the process (items 5, 7 (9), 12 and/or 15). 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: Controls for Chlorpropham

Note: Please refer to the regulations for the requirements prescribed for each control and the modifications listed as set out in section 4 of this document.

Table A2.1: Controls for chlorpropham – codes, regulations and variations.

Control Code[7]	Regulation[8]	Topic	Variations
Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001			
T1	11-27	Limiting exposure to toxic substances	*This control only applies to use of chlorpropham as a pesticide.* No PDE, ADE or TEL values are set at this time.
T2	29, 30	Controlling exposure in places of work	No WES values are set at this time.
T4	7	Requirements for equipment used to handle hazardous substances	
T5	8	Requirements for protective clothing and equipment	
T7	10	Restrictions on the carriage of toxic or corrosive substance on passenger service vehicles	
E1	32-45	Limiting exposure to ecotoxic substances	*This control only applies to use of chlorpropham as a pesticide.* No EEL values are set at this time and the default EELs are deleted.
E2	46-48	Restrictions on use within application area	As no EELs have been set, no application rate is able to be set under this regulation. **However, an application rate is set as an additional control under section 77A.**
E5	6	Requirements for keeping records of use	
E6	7	Requirements for equipment used to handle hazardous substances	
Hazardous Substances (Identification) Regulations 2001			
I1	6, 7, 32-35, 36 (1)-(7)	General identification requirements Regulation 6 – Identification duties of suppliers	

[7] Note: The numbering system used in this column relates to the coding system used in the ERMA New Zealand Controls Matrix. This links the hazard classification categories to the regulatory controls triggered by each category. It is available from the ERMA New Zealand website www.ermanz.govt.nz/resources and is also contained in the ERMA New Zealand User Guide to the HSNO Control Regulations.

[8] These Regulations form the controls applicable to this substance. Refer to the cited Regulations for the formal specification, and for definitions and exemptions.

Control Code[7]	Regulation[8]	Topic	Variations
		Regulation 7 – Identification duties of persons in charge Regulations 32 and 33 – Accessibility of information Regulations 34, 35, 36(1)-(7) – Comprehensibility, Clarity and Durability of information	
I3	9	Priority identifiers for ecotoxic substances	
I8	14	Priority identifiers for toxic substances	
I9	18	Secondary identifiers for all hazardous substances	
I11	20	Secondary identifiers for ecotoxic substances	
I16	25	Secondary identifiers for toxic substances	
I17	26	Use of Generic Names	
I18	27	Use of Concentration Ranges	
I19	29-31	Alternative information in certain cases Regulation 29 – Substances in fixed bulk containers or bulk transport containers Regulation 30 – Substances in multiple packaging Regulation 31 – Alternative information when substances are imported	
I21	37-39, 47-50	Documentation required in places of work Regulation 37 – Documentation duties of suppliers Regulation 38 – Documentation duties of persons in charge of places of work Regulation 39 – General content requirements for documentation Regulation 47 – Information not included in approval Regulation 48 – Location and presentation requirements for documentation	

Control Code[7]	Regulation[8]	Topic	Variations
		Regulation 49 – Documentation requirements for vehicles Regulation 50 – Documentation to be supplied on request	
I23	41	Specific documentation requirements for ecotoxic substances	
I28	46	Specific documentation requirements for toxic substances	
I29	51-52	Duties of persons in charge of places with respect to signage	
I30	53	Advertising corrosive and toxic substances	
Hazardous Substances (Packaging) Regulations 2001			
P1	5, 6, 7 (1), 8	General packaging requirements Regulation 5 – Ability to retain contents Regulation 6 – Packaging markings Regulation 7(1) – Requirements when packing hazardous substance Regulation 8 – Compatibility Regulation 9A and 9B – Large Packaging	
P3	9	Packaging requirements for substances packed in limited quantities	
P13	19	Packaging requirements for toxic substances	
P15	21	Packaging requirements for ecotoxic substances	
PG3	Schedule 3	The tests in Schedule 3 correlate to the packaging requirements of UN Packing Group III (UN PGIII).	
PS4	Schedule 4	This schedule describes the minimum packaging requirements that must be complied with when a substance is packaged in limited quantities	
Hazardous Substances (Disposal) Regulations 2001			
D4	8	Disposal requirements for toxic and corrosive substances	

Control Code[7]	Regulation[8]	Topic	Variations
D5	9	Disposal requirements for ecotoxic substances	
D6	10	Disposal requirements for packages	
D7	11, 12	Disposal information requirements	
D8	13, 14	Disposal documentation requirements	
Hazardous Substances (Emergency Management) Regulations 2001			
EM1	6, 7, 9-11	Level 1 emergency management information: General requirements	
EM6	8(e)	Information requirements for toxic substances	
EM7	8(f)	Information requirements for ecotoxic substances	
EM8	12-16, 18-20	Level 2 emergency management documentation requirements	
EM11	25-34	Level 3 emergency management requirements – emergency response plans	
EM13	42	Level 3 emergency management requirements – signage	
Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004			
Regulations 4 to 43 where applicable		The Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004 prescribe a number of controls relating to tank wagons and transportable containers and must be complied with as relevant.	
Section 77 and 77A Additional Controls			

(1) Prohibition on use of chlorpropham

(1) No person may use chlorpropham for any purpose other than—

(a) for research and development; or

(b) as an ingredient or component in the manufacture of another substance or product;

(2) Despite subclause (1)(a), research and development using chlorpropham does not include investigation or experimentation in which the substance is discharged, laid or applied in or to the outdoor environment;

(3) Despite subclause (1), chlorpropham may be applied in storage warehouses for use as a sprout inhibitor on potatoes, provided that —

(a) application is made using a fogging machine, externally located to the treatment warehouse; and

(b) the maximum application rate of chlorpropham used is:

Control Code[7]	Regulation[8]	Topic	Variations

(i) 0.0145 kg / 1,000 kg potatoes in bulk stores; or

(ii) 0.0215 kg / 1,000 kg potatoes in box stores, and

(c) no person without PPE shall enter treated areas until after 2 hours of mechanical ventilation or 4 hours of passive ventilation. If visible aerosol remains after these periods, no persons without PPE may enter until aerosol has settled.

(2) Specification of chlorpropham

(1) Any person who –

(a) imports into New Zealand chlorpropham, which that person has not previously manufactured or imported; or

(b) had previously imported chlorpropham, but has since changed the source of manufacture for that hazardous substance,

(c) must provide to the Authority in writing the information required by subclauses (3) and (4).

(2) The information required by subclause (1) must be provided –

(a) prior to the substance being imported; and

(b) in the case of chlorpropham to which subclause (1)(b) applies –

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

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

(3) The information to be provided is –

(a) the name and address of the manufacturer of chlorpropham (as appropriate);

(b) the specification of chlorpropham (as appropriate) including –

the manufacturer's specifications including purity of the hazardous substance, isomeric ratio where applicable, maximum impurity content and evidence to support these, including details of analytical methods used. Where chlorpropham is produced at more than one manufacturing site, this information must be provided for each site separately;

(c) the identity of any impurity, its origin, and the nature of its relationship to the active component when the impurity is present at a concentration of 10g/kg or more;

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

Control Code[7]	Regulation[8]	Topic	Variations
		impurity is present at a concentration of less than 10g/kg. (4) Information on an impurity that is required under subclause (3) must include – (a) its chemical name; (b) its Chemical Abstract Service Registry number (if available); and (c) its maximum concentration in the substance; (5) The maximum concentration of chloroaniline in chlorpropham shall be 250 mg/kg.	