Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

4 July 2019

Overview

Substance	Moddus Evo
Application code	APP203771
Application type	To modify an existing approval for a hazardous substance under Section 63A of the Hazardous Substances and New Organisms Act 1996 (“the Act”)
Applicant	Syngenta Crop Protection Limited
Purpose of the application	The purpose of this application is to amend the maximum application limit, both application rate and number of applications to ryegrass seed crops for Moddus Evo (HSR100976).
Submissions received	Turley Farms Limited New Zealand Grain and Seed Trade Association Federated Farmers of New Zealand
Information requests and time waivers	The timeframe for consideration of this application was waived under section 59 of the Act.
Considered by	A Decision-Making Committee of the Environmental Protection Authority Dr Derek Belton – Chair Dr Kerry Laing Dr John Taylor
Decision	Modified reassessment approved
Approval code	**HSR100976**
Hazard classifications	3.1D, 6.1E(oral), 6.1E(inhalation), 6.4A, 9.1D, 9.3C

Application dates	
Date application received	28 January 2019
Submission period	12 February 2019 – 26 March 2019
Consideration date	29 May 2019
Date decision signed	4 July 2019

Executive summary

Moddus Evo is a liquid dispersible concentrate formulation containing 250 g/L of the active ingredient trinexapac-ethyl. It was approved under the Act on 11 November 2014. It is used as a plant growth regulator for use in wheat, barley, ryegrass, and oat crops.

The application to modify the existing approval for Moddus Evo was made by Syngenta Crop Protection Limited ("Syngenta") and was publicly notified in accordance with section 53 of the Act.

During the submission period, three submissions were received on the application. All three of the submissions were in support of the application. Two submitters indicated in their submissions that they wished to be heard at a hearing, however later withdrew their wish to be heard.

Prior to the consideration date, the Decision-Making Committee ('the Committee') requested clarification on two points. The first, expanding on the background of the initial approval and the basis for the grounds to reassess this substance. The second, addressing points raised by the applicant and submitters with regard to inconsistencies in application restriction controls applied to trinexapac-ethyl-containing substances. These questions were addressed, and provided to the Committee in an addendum to the Staff Report prior to consideration.

After considering all relevant information available, the Committee decided that it had sufficient information for making a decision.

The Committee assessed the risks posed by Moddus Evo and determined that they would be negligible with controls. The Committee assessed the benefits associated with the increase in application parameters of Moddus Evo, and determined that they would be non-negligible.

The Committee considered all the effects associated with the substance. They considered that the positive effects of the substance outweigh the adverse effects and decided to approve the application to modify the approval for Moddus Evo.

Table of Contents

1 Background

1.1 Moddus Evo is a liquid dispersible concentrate formulation containing 250 g/L of the active ingredient trinexapac-ethyl. It is used as a plant growth regulator for use in wheat, barley, ryegrass, and oat crops.

1.2 Trinexapac-ethyl inhibits gibberellin synthesis and thus slows plant growth. The reduction in cell elongation leads to thicker and stronger stems that help the plant maintain a more vertical posture. By preventing plants from falling horizontally (lodging), seed harvest is enhanced.

1.3 Moddus Evo was first assessed via section 28(2)(b) of the Act; that is, a rapid assessment with least degrees of hazard. As such, full quantitative human health and environmental risk assessments were not conducted. Moddus Evo was approved with controls on 11 November 2014 under approval number HSR100976. In approving Moddus Evo, a number of controls were applied to the approval to manage risks associated with the substance. One of the controls applicable to HSR100976 is the application restriction control set under section 77A of the Act:

"This substance must not be applied at application rates exceeding 800 ml/ha (equivalent to 200 g trinexapac-ethyl/ha), with a maximum of one application per season".

1.4 The maximum application rate restriction control was set based upon information provided by the applicant about the maximum proposed use parameters of Moddus Evo.

1.5 At the time Moddus Evo was approved, four substances intended for use on ryegrass seed were already approved. Three of these substances were approved with controls, however did not include a maximum application rate restriction control, whereas one substance was approved with controls, including a maximum application rate restriction control.

1.6 Syngenta applied for grounds to reassess Moddus Evo, to increase the application rate and application frequency of Moddus Evo (APP203374). A Decision-Making Committee established that grounds existed under section 62 of the Act on 20 September 2018. The decision was made on the basis that significant new information relating to the effects of the substance had become available. That is, a human health and environmental risk assessment provided by the applicant assessing the risks of the proposed increase in application rate and frequency of Moddus Evo.

2 Process, consultation and notification

Lodgement and formal receipt

2.1 The application to reassess Moddus Evo was lodged on 4 December 2018. It was formally received on 28 January 2019. In their application to reassess Moddus Evo, Syngenta requested that the following aspects of the approval be reassessed:

- The maximum application rate control be changed from 200 g active ingredient per hectare (g ai/ha) to 600 g ai/ha for ryegrass seed crop, and
- The maximum number of applications permitted per year (at a maximum of 200 g ai/ha) be changed from 'one application per season' to 'two applications per season' for ryegrass seed crop.

Scope of application

2.2 The EPA's Chief Executive considered the content of the application and decided to use the EPA's discretionary power in section 63A(1) of the Act to proceed with the application as a modified reassessment. It was decided that the scope of the modified reassessment would be limited to an assessment of changes to controls, relating to the following:

- Maximum application rate
- Maximum number of applications permitted per season.

Notification of application

2.3 The General Manager Hazardous Substances and New Organisms decided not to use the EPA's discretionary power in section 63A(4) of the Act to target the consultation on this application, and it was publicly notified in accordance with section 53 of the Act.

2.4 The application was open for submissions from 12 February 2019 to 26 March 2019.

2.5 The Ministry for the Environment, the Ministry of Health, the Agricultural Compounds and Veterinary Medicines (ACVM) group of the Ministry for Primary Industries, and the Department of Conservation, were advised of the application and notified of the submission period.

2.6 WorkSafe New Zealand ("WorkSafe") provided email comments on this application which have been incorporated into the Staff Report[1].

Submissions received

2.7 Three submissions were received for this application. The submissions were from Turley Farms Limited, New Zealand Grain and Seed Trade Association, and Federated Farmer of New Zealand (Arable Industry Group). All three submissions expressed their support for this application.

2.8 Two submitters requested to be heard in their original submissions, however subsequently withdrew their wish to be heard. Consequently, no public hearing was held for this application.

2.9 All three submitters noted that grass seed is a valuable crop to New Zealand, and noted published trial work which shows increases in seed yields after increasing trinexapac-ethyl application rates and having split application timings.

2.10 The Committee took account of these submissions in making its decision. The Committee also noted that the EPA Staff Report responded to the submissions and took account of these submissions in the benefits assessment.

Time waiver

2.11 The timeframe for consideration of this application was waived under section 59 of the Act to allow for a Decision-Making Committee to be formed.

3 The EPA Staff Report

3.1 The Staff Report is the EPA review of the application and available data regarding the substance. It provides information to assist the Committee to make its decision.

[1] Paragraph 5.19 of the Staff Report for APP203771

3.2 Confidential information was provided by the applicant, which was taken into account during the assessment of Moddus Evo. The confidential information included an environmental and human health risk assessment, and a letter of support discussing the efficacy of higher application rates.

3.3 The EPA conducted quantitative human health and environmental risk assessments to assess the risks of Moddus Evo from either an application rate of 600 g ai/ha once per season, or an application rate of 200 g ai/ha up to twice per season.

3.4 The Staff Report stated that risks to human health and the environment from the proposed use of Moddus Evo were considered to be negligible with controls in place, and provided that application rate and frequency restriction controls are applied, as well as limiting application to ground-based methods only.

3.5 The EPA identified a suite of prescribed controls based on the hazard classifications of Moddus Evo. The EPA also considered variations to these controls, and the addition of extra controls, in accordance with section 77 and section 77A of the Act.

3.6 The Staff Report concluded that the proposed use of Moddus Evo would result in negligible risks to human health and the environment, when appropriate controls are in place and followed, and that the potential benefits of using Moddus Evo were non-negligible. Further, the EPA recommended that the classification of Moddus Evo be amended to include 9.3C (terrestrial vertebrate toxicity).

4 Approval re-issue

4.1 A section 63A modified reassessment of a release approval is subject to sections 77, 77A and 77B of the Act. Therefore, the EPA Notice controls will apply to the modified approvals with transitional periods for some obligations.

4.2 As a consequence of amendments to the Act relating to workplace health and safety reforms, all approvals issued before 1 December 2017 will be reissued in order to refer to the EPA Notices. Approvals subject to a modified reassessment must be reissued, under clause 4(3) of Schedule 7 of the Act, prior to making a decision on the modified reassessment. This is to ensure that the resulting approval satisfies the requirements of the reissue process and the decision of this reassessment.

4.3 The approval of Moddus Evo was therefore reissued on 6 May 2019 prior to the consideration of this modified reassessment. From this date, the EPA Notice controls apply, with a transitional period that ends on 30 November 2021 for the following notices:

- Hazardous Substances (Labelling) Notice 2017
- Hazardous Substances (Packaging) Notice 2017
- Hazardous Substances (Safety Data Sheet) Notice 2017.

5 Consideration

Information available for consideration

5.1 The information available to the Committee for consideration of this application consisted of:

- the application form

- confidential material submitted by the applicant with the application form, including their environmental and human health risk assessments, and a letter of support discussing the efficacy of higher application rates
- a 'Foundation for Arable Research' update report, Edition 123 dated Friday 29 September 2017, submitted by the applicant as supporting documentation to their benefit claims
- the submissions
- information received from WorkSafe
- the science memorandum containing the EPA risk assessment
- the staff report and the addendum to the staff report
- EPA cultural assessment.

5.2 After considering all relevant information, the Committee decided that it had sufficient information to make a decision on this application. Further comments on this information can be found below.

Hazardous properties

5.3 The hazardous properties of Moddus Evo were determined in the original approval. The physical and toxicity hazard classifications of Moddus Evo were not reviewed as part of this application. However, new information was provided by the applicant for the active ingredient, trinexapac-ethyl, which supports a 9.3C classification of Moddus Evo.

5.4 The hazardous properties of Moddus Evo are therefore updated to include the 9.3C vertebrate toxicity classification.

5.5 The classification of Moddus Evo is summarised below in Table 1:

Table 1 Hazard classifications of Moddus Evo

Hazard	Classification
Flammable liquid	3.1D
Acute toxicity (oral)	6.1E
Acute toxicity (inhalation)	6.1E
Eye irritancy/corrosivity	6.4A
Aquatic ecotoxicity	9.1D
Terrestrial vertebrate ecotoxicity	9.3C

5.6 The Committee considered that the classification of Moddus Evo should be amended to reflect the classification proposed by the staff in the staff report.

Proposed modification of controls

5.7 The suite of controls proposed by the EPA, and considered by the Committee are detailed in full in Appendix A of the Staff Report. The control suite included:

- prescribed controls, that is those triggered by the hazard classifications of Moddus Evo
- variations to the prescribed controls in accordance with s77 of the Act
- additional controls, proposed in accordance with s77A of the Act.

Assessment of risks

5.8 The Committee took into account the EPA risk assessment for Moddus Evo, as detailed in the Staff Report and Science Memorandum. The key points are summarised below.

Risks during manufacture, packaging, importation, transportation, storage and disposal

5.9 The Committee considered that the risks during manufacture, packaging, importation, transportation, storage and disposal will remain at a negligible level, given that exposure is unlikely to occur and that the proposed controls and other legislative requirements will sufficiently mitigate the risks associated with these stages of the substance lifecycle. These include the existing Hazardous Substances Notices around packaging, identification, emergency management and disposal of hazardous substances, the Land Transport Rule 45001, Civil Aviation Act 1990, Maritime Transport Act 1994 and New Zealand's health and safety at work requirements.

Risks during use

5.10 The Committee noted that there is the potential for exposure to humans and the environment to occur during the use phase of the substance and considered the human health and environmental risk assessments provided by the EPA.

Human health effects

5.11 The Committee noted that the EPA conducted a quantitative risk assessment with the higher application parameters and considered the comments from Worksafe New Zealand. In the original assessment of Moddus Evo, these use patterns were not identified and therefore had not been assessed prior to this modified reassessment application.

5.12 The Committee noted that the predicted exposures during mixing, loading, and application by operator were below the acceptable operator exposure level (AOEL), and so considered the risks to be negligible.

5.13 The Committee noted that the human health hazard classifications of the substance do not trigger specific PPE requirements. However, the Committee noted that there are obligations under the Health and Safety at Work (Hazardous Substances) Regulations to ensure equipment is appropriate (Regulations 13.7) and any duties of the Person Conducting a Business or Undertaking (PCBU) to provide personal protective equipment under the Health and Safety at Work (General Risk and Workplace Management) Regulations to ensure risks to the health and safety of workers is minimized. Therefore, the Committee noted that it is recommended that personal protective equipment (gloves and goggles) be used when mixing and loading the substance to protect against the potential eye irritation effects of the substance.

5.14 The Committee noted that the predicted exposures to bystanders and re-entry workers were below the AOEL, and so considered the risks to be negligible.

5.15 The Committee noted that the control to limit the amount of toluene permitted in the active ingredient (trinexapac-ethyl) component, which was set in the original decision, is still appropriate.

5.16 The Committee considered that the proposed increase in either application rate or application frequency of Moddus Evo would not pose risks to human health if appropriate controls are in place.

Environmental effects

5.17 The Committee noted that the applicant provided their own quantitative risk assessment, including a list of endpoints. The Committee also noted that the EPA compared these to the values on the EPA substance database and used the most conservative values for the risk assessment.

5.18 The Committee considered the risks to aquatic organisms, groundwater and sediment-dwelling organisms, soil organisms, non-target plants, birds, and pollinators and non-target arthropods, from the proposed use of Moddus Evo, to be negligible.

5.19 The Committee considered that the risks to the environment from an increase in either application rate or application frequency of Moddus Evo would be negligible with appropriate controls in place, including application rate and application restriction controls, as well as limiting application to ground-based methods only.

Assessment of risks to society, the community and the market economy

5.20 The Committee noted that no risks to society, the community and the economy from the approval of Moddus Evo at the higher application rates and frequency, were identified. The Committee therefore did not consider this further.

Assessment of benefits

5.21 The Committee noted that the applicant made one benefit claim of Moddus Evo in the application:

"Higher rates of Moddus Evo will allow farmers to realise higher yields per hectare with increased margin over costs, thereby contributing to their profits and the sustainability of arable agriculture"

5.22 The submitters further supported this benefit claim in the submissions, and in some instances provided additional supporting information.

5.23 The Committee noted the EPA had qualitatively assessed the benefit claim, and noted the EPA rated this as a medium benefit in the Staff Report.

5.24 The Committee considered the proposed benefit as non-negligible.

Cultural assessment

5.25 The Committee noted that the EPA assessed the potential effects of the application on the economic, social, and cultural well-being of Māori, and the relationship of Māori with the environment, in accordance with sections 5(b), 6(d) and 8 of the Act.

5.26 The Committee considered that with the controls proposed in place, the impact of a higher application parameters of Moddus Evo on the relationship of Māori to the environment would be negligible. The Committee considered that the application is likely to be consistent with the principles of the Treaty of Waitangi.

New Zealand's international obligations

5.27 The Committee noted there were no international obligations regarding Moddus Evo or its active ingredient, trinexapac-ethyl.

Discussion regarding control inconsistencies between trinexapac-ethyl-containing substances

5.28 The Committee noted that the applicant and submitters highlighted inconsistencies regarding application restriction controls across trinexapac-ethyl-containing substances intended for use on ryegrass seed crops.

5.29 The Committee noted that inconsistencies arise due to substances being transferred into the regime (through the Hazardous Substances Transfer Notices) without application restriction controls. Changes and improvements in operating procedures over time mean that the controls applied to post-transfer approvals tend to include a greater degree of restriction, which is inconsistent with those substances approved earlier under the HSNO regime. A reassessment is required to amend outdated controls for hazardous substances that are inconsistent with more recent approvals of similar substances.

5.30 Any person may apply to have a substance (or substances) reassessed under section 63 or section 63A of the Act. Applications must establish grounds to reassess the substance(s) under section 62 of the Act.

Amendments to proposed controls by the Committee

5.31 The Committee noted the wording of the proposed application restriction control as proposed in the Staff Report did not appropriately reflect the outcomes of the assessment conducted. Thus, the wording of the application restriction control is reworded to ensure that the maximum application parameters for the two application scenarios are clear and distinct, as follows:

> The following application restrictions apply:
>
> > The substance may be applied up to a maximum application rate of either—
> >
> > (a) 600 g ai/ha, once per season; or
> >
> > (b) 200 g ai/ha, up to two times per season.

5.32 In accordance with section 63A(6)(b) of the Act, the Committee took into account the proposed suite of controls and noted that these aligned with best international practice for the mitigation of risks posed to human health and the environment by hazardous substances.

5.33 The Committee determined that the controls detailed in Appendix A will apply as soon as this decision is published or at the latest at the end of the transitional period specified in Tables A-1, A-2 and A-3 in Appendix A.

6 Conclusion and decision

6.1 Pursuant to sections 63A(6) of the Act and section 32 of the Hazardous Substances and New Organisms (Methodology) Order 1998 ("the Methodology"), the Committee considered this application to modify an approval. In doing so, the Committee applied all the relevant sections of the Act and clauses of the Methodology, as detailed in Appendix B.

6.2 The Committee considered all the effects associated with the substance. They considered that the benefits of the higher application parameters of Moddus Evo outweigh the risks, considered as negligible when the suite of controls listed in Appendix A apply. They, therefore, considered that the positive effects of the higher application parameters of Moddus Evo outweigh the adverse effects.

6.3 In making its decision, the Committee took into account best international practices and standards for the safe management of hazardous substances.

6.4 Consequently, the Committee determined that the application be approved.

Signed by: **Dr Derek Belton**	**Date: 4 July 2019**
Chair, Decision Making Committee **Environmental Protection Authority**	

Appendix A: Controls applying to Moddus Evo

The controls in Table A-1 are prescribed by the EPA Notices. The controls that have been varied by section 77 of the Act are in Table A-2. The additional controls set under section 77A are in Table A-3.

Table A-1 Prescribed controls

Control code	Legislative instrument	Control description	Date of effect
LAB	EPA Labelling Notice 2017	Requirements for labelling of hazardous substances	Before 30 November 2021
PKG	EPA Packaging Notice 2017	Requirements for packaging of hazardous substances	Before 30 November 2021
SDS	EPA Safety Data Sheet Notice 2017	Requirements for safety data sheets for hazardous substances	Before 30 November 2021
DIS	EPA Disposal Notice 2017	Requirements for disposal of hazardous substances	Immediate
HPC-1	EPA Hazardous Property Controls Notice 2017 Part 1	Hazardous Property Controls	Immediate
HPC-3	EPA Hazardous Property Controls Notice 2017 Part 3	Hazardous Property Controls	Immediate
HPC-4A	EPA Hazardous Property Controls Notice 2017 Part 4A	Hazardous Property Controls	Immediate
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B	Hazardous Property Controls	Immediate

Table A-2 Controls varied under section 77

Control code	Legislative instrument	Variation	Date of effect
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B – clause 50(1)	*The following application restrictions apply:* The substance may be applied up to a maximum application rate of either— (a) 600 g ai/ha, once per season; or (b) 200 g ai/ha, up to two times per season.	Immediate

Table A-3 Additional controls under section 77A

Code	Control	Date of effect
Application method	A person must only use this substance by ground-based methods only	Immediate
Max impurity	The maximum level of an impurity in the technical grade active material for this substance is set. The maximum level of toluene in the trinexapac-ethyl component of this substance must not exceed 3000 mg/kg (0.3%)	Immediate

Health and Safety at Work (HSW) Requirements

Note: these requirements are not set for the substance under this approval but apply in their own right under the HSW Act and HSW (Hazardous Substances) Regulations according to the classification of the substance. They are listed here for information purposes only.

Code	Regulation	Description	Extra information
HSW2-1	Reg 2.1 - 2.4	Workplace labelling of hazardous substance containers	
HSW2-2	Reg 2.5-2.10	Signage	
HSW2-3	Reg 2.11	Safety data sheets	
HSW2-4	Reg 2.12-2.14	Packaging	
HSW3-1	Reg 3.1	Inventory	
HSW3-2	Reg 3.2 -3.3	Managing risks associated with hazardous substances	
HSW4-2	Reg 4.5-4.6	Information, instruction, training and supervision	
HSW5-1	Reg 5.2 - 5.5	Fire extinguishers	
HSW5-2	Reg 5.6-5.13	Emergency response plans	
HSW8-2	Reg 8.3 - 8.4	Requirements for public transportation of class 1 to 5 substances	
HSW10-3	Reg 10.5	Requirement to segregate class 2, 3, and 4 substances	
HSW10-5	Reg 10.8 - 10.20	Requirements to prevent unintended ignition of class 2.1.1, 2.1.2 and 3.1 substances	
HSW10-12	Reg 10.30 - 10.33	Secondary containment for class 3 and 4 pooling substances	
HSW11-1	Part 11	Controls relating to adverse effects of unintended ignition of class 2 and 3.1 substances	
HSW13-2	Reg 13.7	Duty of PCBU who directs work using class 6, 8.1, 8.2, or 8.3 substances to ensure equipment is appropriate	
HSW13-8	Reg 13.17	Prohibition on use of substance in excess of tolerable exposure limit	

Code	Regulation	Description	Extra information
HSW13-9	Reg 13.18	Duty of PCBU to ensure prescribed exposure standards for class 6 substances not exceeded	No WES values have been set for any components of this substance at this time.
HSW16-1	Part 16	Requirements for tank wagons and transportable containers	
HSW17-1	Part 17	Requirements for stationary container systems	

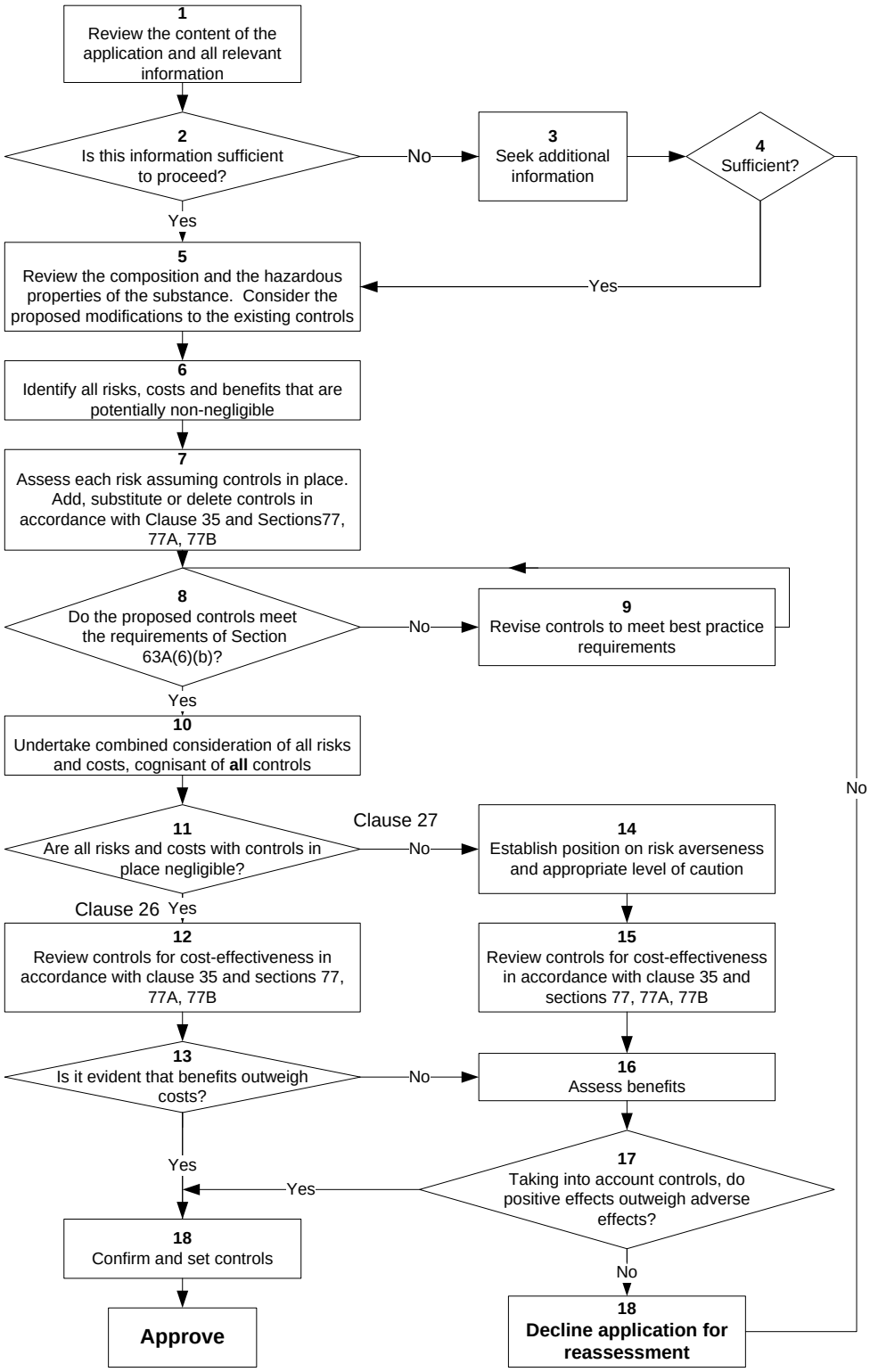
Appendix B: Decision Path

Context

This decision path describes the decision-making process for applications for a modified reassessment for amendments to hazardous substances approvals. These applications are made and determined under section 63A of the HSNO Act.

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.



Explanatory Notes

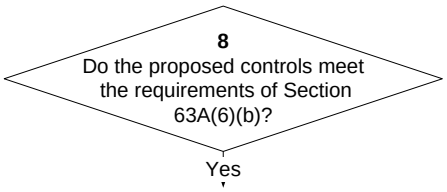
Item 1:	**Review the content of the application and all relevant information** Review the application, the E&R Report, and information received from experts and that provided in submissions (where relevant) in terms of section 28(2) of the Act and clauses 8, 15, 16 and 20 of the Methodology. While section 63A is not mentioned in section 53 (public notification), sections 63A(4) and (5) provide discretion for the HSNO decision maker 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 HSNO decision maker 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 HSNO decision maker 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[2]** The modified reassessment process concentrates on a specific aspect of the 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.

[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.

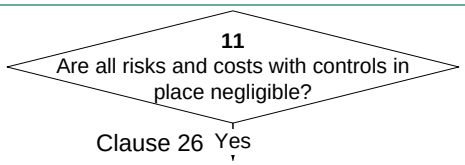
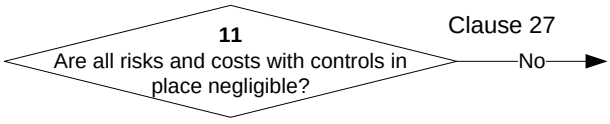
	Costs and benefits are defined in the Methodology as the value of particular effects. However, in most cases these 'values' are not certain and have a likelihood attached to them. Thus costs and risks are generally synonymous and may be addressed together. Examples of costs that cannot be considered 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[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 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.	

[3] 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.

[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.

	This assessment includes consideration of how cautious the HSNO decision maker 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 HSNO decision maker's approach to risk (clause 33 of the Methodology) or how risk averse the HSNO decision maker should be in giving weight to the residual risk, where residual risk is the risk remaining after the imposition of controls. See EPA 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 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.
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.

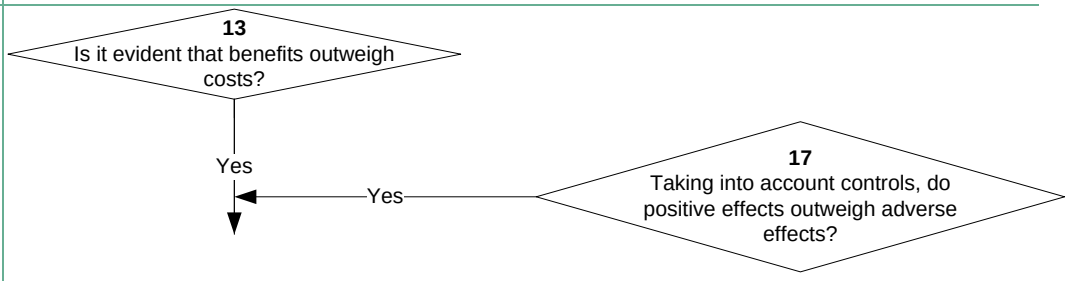
[5] http://www.epa.govt.nz/Publications/Approach-to-Risk.pdf

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[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 HSNO decision maker 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 HSNO decision maker'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

[6]Technical Guide 'Decision making' section 4.9.3. Where risks are negligible and the costs accrue only to the applicant, no explicit cost benefit analysis is required. In effect, the HSNO decision maker 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'

	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 HSNO decision maker's approach to uncertainty or how cautious the HSNO decision maker 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 HSNO decision maker 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 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 HSNO decision maker 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.

[7] Clause 13 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 HSNO decision maker concludes that the application for reassessment may be declined if there is insufficient information. (from item 17) The HSNO decision maker 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.
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.