Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

2 August 2019

Overview

Substance	Meteor
Application code	APP203786
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	AgriNova NZ Limited (AgriNova)
Purpose of the application	To reassess the plant growth regulator product Meteor (HSR101023) to reduce the maximum application rate and so reduce the restricted entry interval
Submissions received	none
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 Louise Malone – Chair Dr Ngaire Phillips
Decision	Modified reassessment approved
Approval code	**HSR101023**
Hazard classifications	6.1D (All), 6.1D (I), 6.1D (D), 6.1D (O), 6.3B, 9.1A (All), 9.1A (M), 9.2A, 9.3C.

Application dates	
Date application received	1 March 2019
Submission period	15 March 2019 – 1 May 2019
Consideration date	5 July 2019
Date decision signed	2 August 2019

Executive summary

Meteor is a plant growth regulator containing 700 g/kg of the active ingredient metamitron. Meteor comes in a water dispersible granule form. The substance is sprayed on apples and pears to reduce fruit numbers.

AgriNova NZ Limited ("AgriNova") applied to reassess Meteor under section 63 of the Hazardous Substances and New Organisms Act (HSNO Act; "the Act"). AgriNova sought to reduce the maximum application rate control from 700 g ai/ha to 518 g ai/ha so as to reduce the restricted entry interval (REI) and buffer zone controls.

The notification period for members of the public and other interested parties to provide written submissions was open from 15 March 2019 to 1 May 2019. No submissions were received.

In the staff report; the EPA re-evaluated the restricted entry interval using the lower proposed application rate and product-specific dislodgeable foliar residue study data provided by the applicant. The EPA recommended that the restricted entry interval be reduced to four days without gloves or 1 day with gloves. Buffer zones were also re-calculated at the lower proposed application rate. The EPA recommended that the buffer zone remain unchanged at 15 m, for the purposes of protecting non-target plants.

After considering all relevant information available, the decision-making committee ("the Committee") decided that it had sufficient information to make a decision.

The Committee assessed the risks posed by the changes to controls for Meteor and determined that the risks would be negligible with these new controls. The Committee assessed the benefits associated with the changes to controls and determined that they would be non-negligible.

The Committee considered that the positive effects outweigh the adverse effects and decided to approve the application to modify the approval for Meteor.

Table of Contents

Overview i
Executive summary ii
1 Background 1
2 Process, consultation and notification 1
Lodgement and formal receipt 1
Scope of application 1
Notification of application 2
Submissions received 2
3 The EPA Staff Report 2
4 Approval re-issue 3
5 Consideration 3
Information available for consideration 3
Hazardous properties 3
Proposed modification of controls 4
Assessment of risks 4
Risks during manufacture, packaging, importation, transportation, storage and disposal 4
Risks during use 4
Human health effects 4
Environmental effects 5
Assessment of risks to society, the community and the market economy 5
Assessment of benefits 5
Cultural assessment 5
New Zealand's international obligations 5
6 Conclusion and decision 6
Appendix A: Controls applying to Meteor 7
HSW Requirements 9
Appendix B: Decision Path 11

1 Background

1.1 Meteor is a plant growth regulator containing 700 g/kg of the active ingredient metamitron (CAS#: 41394-05-2). Meteor comes in a water dispersible granule form. The substance is sprayed on apples and pears to reduce fruit numbers.

1.2 The current maximum application rate is set at 700 g ai/ha, twice a year. AgriNova (the applicant) has proposed reducing this to 518 g ai/ha, twice a year. The applicant posits that this is in line with current use and any resulting reduction in the restricted entry interval (also known as re-entry interval) would boost the practicality of their product.

1.3 Meteor was originally approved under application APP202403 on 5 May 2015. The applicant was also AgriNova NZ Limited.

1.4 A section 67A amendment on 24 September 2017 (APP203245) reduced the restricted entry interval from 22 days with gloves or 28 days without gloves, to 15 days with gloves or 21 days without gloves. This amendment occurred because the EPA had adopted new default values for dermal absorption. The change was considered minor in effect.

1.5 Grounds for the reassessment of Meteor were sought in APP203546. A decision-making committee decided, on 12 November 2018, that grounds exist under the factor 'information showing a significant change of use, or a significant change in the quantity manufactured, imported, or developed has become available' (section 62(2)(c) of the Act). The change in application rate was considered a significant change of use.

1.6 The EPA's Chief Executive decided on 05 March 2019 that the application would proceed via a modified reassessment under section 63A of the Act.

2 Process, consultation and notification

Lodgement and formal receipt

2.1 The application to reassess Meteor was lodged on 21 December 2018. It was formally received on 1 March 2019. In their application to reassess Meteor, AgriNova has requested that the following aspects of the approval be reassessed:

- The maximum application rate control be changed from 700g active ingredient per hectare (g ai/ha) to 518 g ai/ha.
- The restricted entry interval be changed from 21 days without gloves/15 days with gloves to 9 days without gloves/7 days with gloves.
- The buffer zones be re-considered at the proposed reduced application rate.

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:

- maximum application rate
- restricted entry intervals
- buffer zones.

Notification of application

2.3 Subsequently, 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 15 March 2019 to 1 May 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 advice on this application which has been incorporated into the Staff Report.

Submissions received

2.7 There were no submissions received on this application.

Time waiver

2.8 The timeframe for consideration of this application was waived under section 59 of the Act in order to allow WorkSafe adequate time to provide advice.

3 The EPA Staff Report

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

3.2 Confidential information was provided by the applicant, which was taken into account during the assessment of Meteor. The confidential information included a product-specific dislodgeable foliar residue study conducted by an independent company, and a short risk assessment calculation of the restricted entry interval.

3.3 The EPA provided a revised restricted entry interval based on the proposed reduced application rate and the new information provided by the applicant. The EPA's recommendation was that at an application rate of 518 g ai/ha a restricted entry interval of four days without gloves, or one day with gloves, is sufficient to manage risk to re-entry workers.

3.4 The EPA reviewed the buffer zone distance at the proposed reduced application rate. The EPA's recommendation was that at an application rate of 518 g ai/ha the downwind buffer zone should remain at 15 metres to sufficiently manage risks to non-target plants.

3.5 The human health and environmental risk assessments were included as appendices to the EPA Staff Report.

3.6 The EPA identified a suite of prescribed controls based on the hazard classifications of Meteor. 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.

3.7 The Staff Report concluded that the proposed use of Meteor poses negligible risks to human health and the environment, when appropriate controls are in place and followed, and that the potential benefits of using Meteor were non-negligible. Further, the EPA recommended that the classification of Meteor be revised to change the inhalation toxicity classification from 6.1B to 6.1D.

4 Approval re-issue

4.1 The EPA now sets default controls using EPA Notices that came into force on 1 December 2017. However, these notices cannot apply to existing approvals until the they are reissued under the Act. Further, on 1 December 2017, any existing prescribed control that was replaced by regulations under the Health and Safety at Work (Hazardous Substances) Regulations 2017 (HSW (HS) Regulations) or safe work instrument ceased to have legal effect.

4.2 When carrying out a modified reassessment on an approval, it is appropriate to reissue the existing approval prior to the decision on the reassessment. This enables any controls that have ceased to have legal effect to be removed and for the new controls from the EPA Notices to be applied before the decision maker makes any relevant changes to controls arising from the reassessment.

4.3 The approval of Meteor was therefore reissued on 27 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 the product-specific dislodgeable foliar residue study conducted by an independent company, and a short risk assessment calculation of the restricted entry interval
- advice received from WorkSafe
- the EPA staff report which included human health and environmental risk assessments as appendices
- a cultural risk assessment produced by the EPA.

5.2 After considering all relevant information, the Committee decided that it had sufficient information to make a decision on this application.

Hazardous properties

5.3 The Committee noted that the majority of the hazard classifications of Meteor were determined in the original application; APP202403. However, since Meteor was first approved, new information about the active ingredient metamitron has emerged. This information supports a 6.1D acute toxicity (inhalation) classification for metamitron rather than a 6.1B.

5.4 As such, Meteor is classified as 6.1D for acute toxicity (inhalation), based on mixture rules.

5.5 The classification of Meteor is summarised below in Table 1:

Table 1 Hazard classifications of Meteor

Hazard	Classification
Acute toxicity (Inhalation)	6.1D
Acute toxicity (Dermal)	6.1D
Acute toxicity (Oral)	6.1D
Skin irritancy	6.3B
Aquatic ecotoxicity	9.1A
Soil ecotoxicity	9.2A
Terrestrial vertebrate ecotoxicity	9.3C

Proposed modification of controls

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

- prescribed controls, that is those triggered by the hazard classifications of Meteor
- 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

5.7 The Committee took into account the EPA risk assessment for Meteor, as detailed in the staff report. The key points are summarised below.

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

5.8 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, hazardous properties, labelling, safety data sheet requirements, 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

5.9 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

5.10 The Committee noted that the EPA did not repeat the work done in the original risk assessment (APP202403). The Committee noted that the changes to human health risk in this reassessment pertained to the reassessment of the restricted entry interval.

5.11 The Committee noted that AgriNova provided their own risk assessment but that due to differences in approach, the EPA conducted is own reassessment of the restricted entry interval.

5.12 The Committee considered the EPA's recommendation, as detailed in the staff report, of restricted entry intervals of four days without gloves or one day with gloves are sufficient to manage risk to re-entry workers.

5.13 The restricted entry interval is now set by WorkSafe under the Health and Safety at Work Act 2015 (HSWA).

Environmental effects

5.14 The Committee noted that the EPA did not repeat the work carried out in the original risk assessment (APP202403). The Committee noted that the changes to environmental risk in this reassessment pertained to the re-evaluation of the buffer zone.

5.15 The Committee considered the EPA's recommendation, as detailed in the staff report, that the downwind buffer zone should remain set at 15 metres so as to sufficiently manage the risk to non-target plants.

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

5.16 The Committee noted that no risks to society, the community and the economy from changes to controls of Meteor were identified. The Committee therefore did not consider this further.

Assessment of benefits

5.17 The Committee noted that the applicant made one benefit claim of Meteor in the application:

"Having a reduced re-entry interval allows more efficient and flexible management of crop by growers (eg. Hand-thinning), better utilisation of staff and enhanced ability to monitor for pests and disease thereby reducing costs and improving saleable yields."

5.18 The Committee considered the proposed benefit to be non-negligible.

Cultural assessment

5.19 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.

5.20 The Committee considered the impact on the relationship of Māori to the environment, due to the changes to controls for Meteor, 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

5.21 No international obligations that may be impacted by the changes to Meteor have been identified.

6 Conclusion and decision

6.1 Pursuant to section 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.

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

6.3 The Committee considered that the risks to human health and the environment posed by changes in controls which apply to the substance are negligible.

6.4 The Committee considered that the benefits presented by changes in controls which apply to the substance are non-negligible.

6.5 The Committee considered that the positive effects due to the changes to controls of Meteor outweigh the adverse effects.

6.6 Accordingly, the Committee considered that:

- The maximum application rate for the substance shall be set at 518 g ai/ha
- Following application, the restricted entry interval is recommended to be four days without gloves, or one day with gloves to manage risks to re-entry workers
- A 15 metre downwind buffer zone applies for non-target plants
- The classification of Meteor for acute toxicity (inhalation) is changed to 6.1D

6.7 Consequently, the Committee decided that the application be approved with controls as listed in Appendix A.

Environmental Protection Authority
Te Mana Rauhī Taiao

Signed by: **Dr Louise Malone**	**Date: 2 August 2019**
Chair, Decision-Making Committee **Environmental Protection Authority**	

Appendix A: Controls applying to Meteor

The controls in Table A-1 are prescribed by the EPA. Those controls that have been varied by s 77 of the Act are in Table A-2, and those set under s 77A of the Act 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
HPC-4C	EPA Hazardous Property Controls Notice 2017 Part 4C	Hazardous Property Controls	Immediate

Table A-2 Controls varied under section 77

Control code	Legislative instrument	Variation	Date of effect
Application restrictions	Section 77 variation to HPC Notice clause 50(1)	The maximum application rate of this substance is 740 g of substance/ha (equivalent to 518 g metamitron/ha) per application, with a maximum application frequency of twice per year, with a minimum interval period of 5 days between applications	Immediate
Buffer zone	Section 77 variation to HPC notice clause 51(1)	The person in charge of the application of this substance and any person applying this substance must ensure that the substance is not applied within 15 m of downwind non-target plants	Immediate
Label	Section 77 variation to Labelling Notice.	The substance label must include the following, or similar, wording: This substance shall be applied via ground-based methods only	Before 30 November 2021

Table A-3 Additional controls under section 77A

Code	Control	Date of effect
Max impurity	The maximum level of the hydrazine impurity in the metamitron component of this substance must be less than 1 g/kg	immediate
Application method	This substance shall be applied via ground-based methods only[1] [1] Ground-based methods of applying pesticides include, but are not limited to, application by ground boom, airblast or knapsack, and do not include aerial application methods	immediate

HSW Requirements

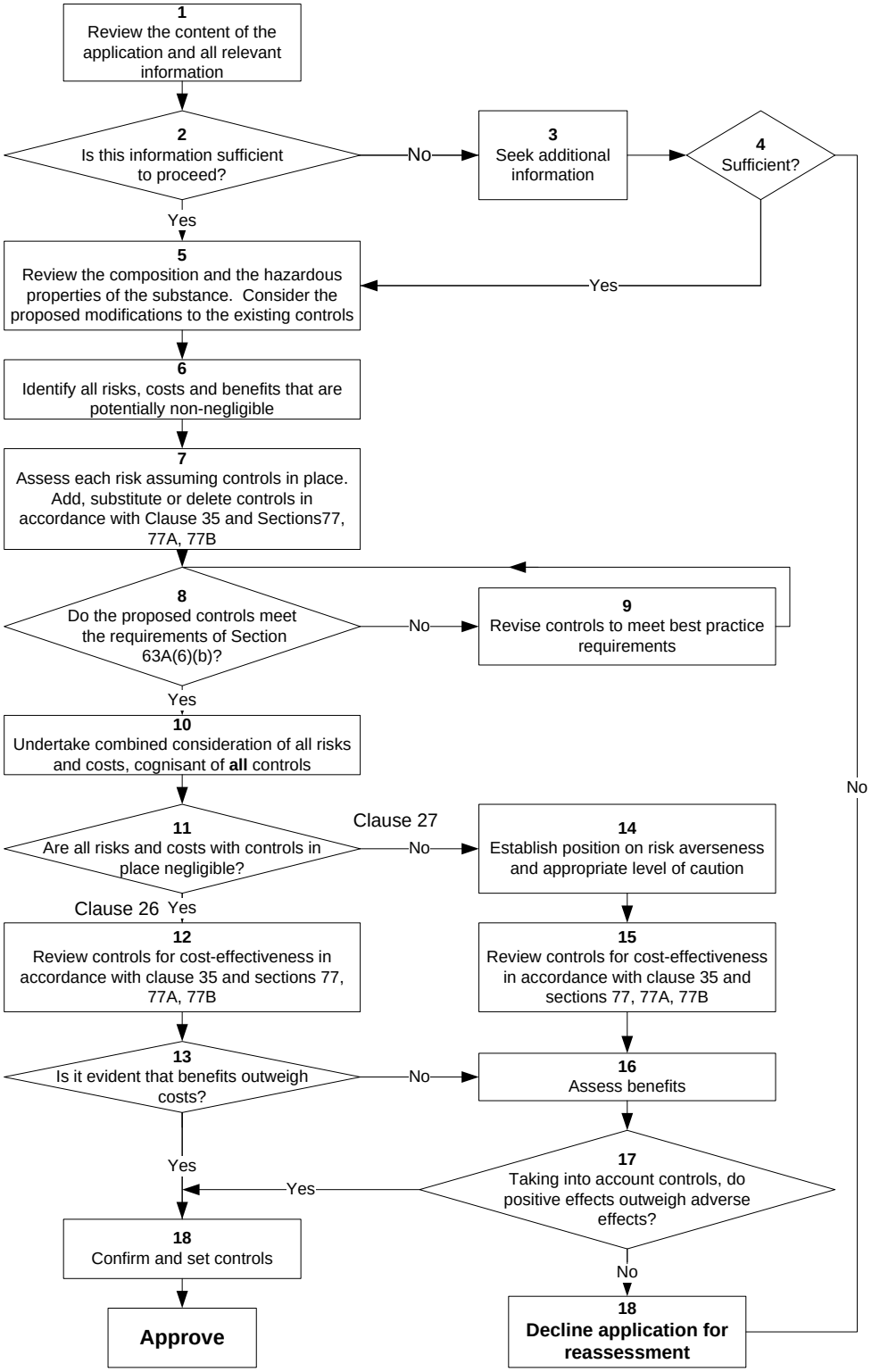
Note: these requirements are not set for the substance under this approval but apply in their own right under the HSW Act and HSW (HS) Regulations according to the classification of the substance. They are listed here for information purposes only.

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	
HSW5-2	Reg 5.6-5.13	Emergency response plans	
HSW13-1	Reg 13.3-13.4	Records of application for class 6 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	
HSW13-3	Reg 13.8	Duty of PCBU who directs work using class 6 and 8 substances to ensure personal protective equipment used	
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.
HSW13-12	Reg13.23-25	Restricted entry intervals	The restricted entry is 4 days without gloves, or 1 day with gloves.
HSW16-1	Part 16	Requirements for tank wagons and transportable containers	

Appendix B: Decision Path

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

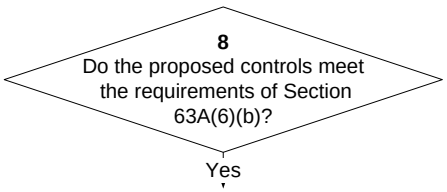
Item 1:	**Review the content of the application and all relevant information** Review the application, the E&R Report, and information received from experts and that provided in submissions (where relevant) in terms of section 28(2) of the Act and clauses 8, 15, 16 and 20 of the Methodology. While section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

[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.

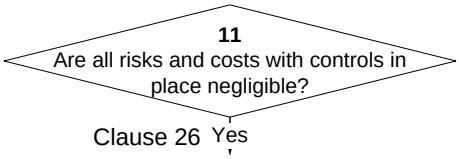
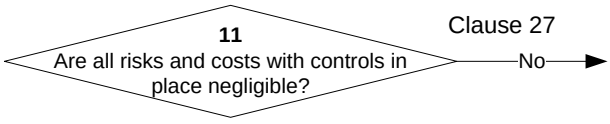
	Costs and benefits are defined in the Methodology as the value of particular effects. However, in most cases these 'values' are not certain and have a likelihood attached to them. Thus costs and risks are generally synonymous and may be addressed together. Examples of costs that cannot be considered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

[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 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 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[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.
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.

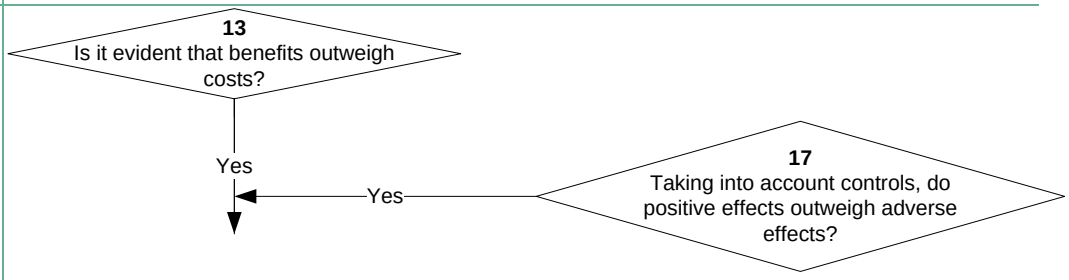
[4] http://www.epa.govt.nz/Publications/Approach-to-Risk.pdf

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 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:	

[5]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'

	(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 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[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 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.

[6] Clause 13 of the Methodology

	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 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.