



## DECISION

5 November 2018

### Summary

Substances	Luna Privilege and Luna Sensation
Application code	APP203261
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	Bayer New Zealand Limited
Purpose of the application	To modify the maximum application rate, number of applications and interval between applications for Luna Privilege and Luna Sensation
Information requests and time waivers	Further information was requested under section 58 of the Act. Consequently, the timeframe for the consideration of this application was waived under section 59 of the Act
Submissions received	Chris Houston, Beef + Lamb New Zealand Michael Stevens, Te Rūnanga Nui o Te Aupouuri Trust Dr Oliver Sutherland, Te Rūnanga o Ngāi Tahu Helen Barnes, TomatoesNZ Inc John Seymour, Vegetables New Zealand Inc Marie Dawkins, Summerfruit New Zealand Roger Andela, Fonterra Co-operative Group Limited Misha Davis, Soil & Health Association of New Zealand Inc.
Considered by	A Decision-Making Committee of the Environmental Protection Authority ("the Committee"): Dr Ngaire Phillips (Chair) Dr Kerry Laing Dr Derek Belton
Decision for Luna Privilege	Approved with controls for a maximum application rate of 600 mL/ha with a maximum of two applications per year with an interval of at least seven days between applications when used on fruiting vegetables in greenhouses

Application for approval to manufacture ESN containing sodium nitrite at 950 g/kg and bait containing sodium nitrite at 100 g/kg (ERMA200570)

Approval code for Luna Privilege	<b>HSR100746</b>
Decision for Luna Sensation	Approved with controls for a maximum application rate of 600 mL/ha with a maximum of three applications per year with an interval of at least seven days between applications when used on stone fruits
Approval code for Luna Sensation	<b>HSR100998</b>

### Application dates

Date application received	1 June 2017
Submission period	16 June – 28 July 2017
Hearing date	2 August – 5 September 2018
Consideration date	5 September – 5 November 2018
Date decision signed	5 November 2018

# 1. Application context

## Background

- 1.1. Luna Privilege is a fungicide used to protect kiwifruit from sclerotinia containing 500 g/L fluopyram as the active ingredient (ai). Luna Privilege was approved for use in New Zealand in 2012 (approval number HSR100746). The modified reassessment seeks to determine whether the maximum application rate of Luna Privilege can be increased from 300 to 600 mL/ha (300 g fluopyram/ha) per application, and the number of applications per year from one to two (with an interval of at least seven days between applications). These changes would allow the use of Luna Privilege to be extended to greenhouse fruiting vegetables (for example tomatoes, capsicums, aubergines, chili, but excluding cucurbits).
- 1.2. Luna Sensation is a protectant and systemic fungicide for the control of powdery mildew in grapes containing 250 g/L fluopyram and 250 g/L trifloxystrobin as the active ingredients. Luna Sensation was approved for use in New Zealand in 2014 (approval number HSR100998). The modified reassessment seeks to determine whether the maximum application rate of Luna Sensation can be increased from 150 to 600 mL/ha (150 g fluopyram/ha and 150 g trifloxystrobin/ha) per application, the number of applications per year from two to three and the minimum interval between applications reduced from ten to seven days. These changes would allow the use of Luna Sensation to be extended to stone fruits (including cherries, peaches, nectarines and apricots).

## Process and consultation

- 1.3. Grounds for the modified reassessments of Luna Privilege and Luna Sensation were granted by a Decision-Making Committee of the Environmental Protection Authority (EPA) on 4 April 2017 (application number APP203182). This decision was made on the basis that significant new information on change in the possible use of the substances had become available.
- 1.4. The application for a modified reassessment of the approvals for Luna Privilege and Luna Sensation was lodged pursuant to section 63A of the Act and was formally received on 1 June 2017.

## Notification to government departments

- 1.5. The Ministry of Health, the Ministry for the Environment, the Department of Conservation and the Agricultural Compounds and Veterinary Medicines (ACVM) group of the Ministry for Primary Industries were notified of the application and the submission period on 1 June 2017 and were invited to comment. No comments were received.
- 1.6. WorkSafe New Zealand (“WorkSafe”) is the agency responsible for overseeing the Health and Safety at Work Act 2015 (HSW Act) and Health and Safety at Work (Hazardous Substances) Regulations 2017 (HSW (HS) Regulations). Therefore, advice was sought from WorkSafe on whether the HSW requirements are adequate to manage the risks associated with the use of these substances in the workplace.

- 1.7. WorkSafe was notified of the application on 1 June 2017 and provided with the appropriate documents in April 2018 to allow them to make this assessment.

### **Public notification**

- 1.8. The application was publicly notified in accordance with section 53 of the Act, and public submissions were sought from 16 June 2017 until 28 July 2017. Eight submissions were received.

### **Request for additional information**

- 1.9. Under section 58 of the Act, further information was requested of the applicant on 21 July 2017. This information relates to the assessment of any particular risks, costs and benefits which arise from the relationship of Māori and their culture and traditions with their taonga, and to the type of application in greenhouses, in particular the application method, and the surface area treated daily, to assess the risks to operators and integrated pest management systems.
- 1.10. The statutory timeframe for consideration of the application was waived on 2 August 2017 under section 59 of the Act to allow the EPA to consider new information provided by the applicant on 2 August 2017.
- 1.11. After the EPA published the science memoranda for Luna Privilege and Luna Sensation and Evaluation and Review report on 19 July 2018, the applicant contacted the EPA on 27 July 2018.
- The applicant had identified a mistake in the human health risk assessment of Luna Privilege
  - The applicant provided further information about the restricted entry interval (REI) for Luna Sensation.
- 1.12. The EPA corrected its human health risk assessment of Luna Privilege, amended the Evaluation and Review report accordingly and provided these updated documents to the Committee and the submitters on 31 July 2018 (ie in advance of the public hearing).

### **Hearing**

- 1.13. The Committee determined that the information was material to the decision making process and agreed that it would allow the further information about the REI to be considered as part of the application and to be presented at the hearing by the applicant.
- 1.14. The hearing was held on 2 August 2018 in presence of the applicant and representatives, the EPA staff, the submitters who wished to be heard (apart from Soil & Health Association of New Zealand Inc.) and WorkSafe. The hearing was adjourned at the end of the day in order to take into consideration the new information provided by the applicant.

### **Submissions received after the hearing**

- 1.15. At the hearing on 2 August 2018, it was decided by the Committee that this new information about the REI would be assessed by the EPA staff. The risk assessment for Luna Sensation and Evaluation and Review report were updated using this new information. The updated documents were made available

on 9 August 2018, providing submitters with an opportunity to submit on the new information between 9 and 17 August 2018.

1.16. One submission was received on 13 August 2018 from Summerfruit NZ, in support of the reduced REI of 1 day as recommended by the EPA in the amended science memorandum for Luna Sensation and amended Evaluation and Review Report for APP203261.

1.17. The hearing was closed on 5 September and the DMC started the consideration of the application.

## Approval re-issue

1.18. A section 63A modified reassessment of a release approval is subject to sections 77, 77A and 77B. Therefore, the EPA Notice controls will apply to the modified approvals. Such approvals must therefore be reissued under clause 4(3) of Schedule 7 of the HSNO Act. The approvals have therefore been reissued prior to the completion of the modified reassessment, on 1 November 2018.

## Information available for consideration

- 1.19. The information available to the Committee for consideration of this application consisted of the:
- application form, including the confidential material submitted by the applicant
  - original applications and associated documents
  - submissions
  - hearing presentations made by the applicant, WorkSafe New Zealand, staff of the EPA and submitters
  - additional information supplied by the applicant at the hearing
  - amended EPA Staff Evaluation and Review Report and amended science memoranda for Luna Privilege and Luna Sensation, incorporating the new information provided by the applicant.
- 1.20. There were 8 submissions received on the application, and 4 submitters were heard at the public hearing.
- 1.21. After considering all relevant information, the Committee decided that it had sufficient information to make a decision on this application.

## Hazardous classifications

1.22. The hazardous properties of Luna Privilege and Luna Sensation remain unchanged since the original applications as no new information was available to inform a review of the hazards. The classifications of Luna Privilege and Luna Sensation are summarised in Table 1 below:

**Table 1: Hazard classifications for Luna Privilege and Luna Sensation**

Hazard	Classification	
	Luna Privilege	Luna Sensation
Acute toxicity (oral)	No	6.1D
Target organ or system toxicity (oral)	6.9B	6.9B
Aquatic ecotoxicity	9.1B	9.1A

Hazard	Classification	
	Luna Privilege	Luna Sensation
Terrestrial vertebrate ecotoxicity	No	9.3C

## 2. Proposed modifications to the approval of Luna Privilege

- 2.1. The suite of controls applied to Luna Privilege under approval HSR100746 included the following maximum application rate control, which was applied under section 77A of the Act:

*This substance shall be applied at a maximum application rate of 300 mL/ha (150g fluopyram/ha) with a maximum of one application per year.*

- 2.2. The modified reassessment sought to determine whether this control could be amended to allow a maximum application rate of 600 mL/ha (300 g fluopyram/ha) per application, with a maximum of two applications per year at an interval of at least seven days between applications.
- 2.3. These changes would allow the use of Luna Privilege to be extended to greenhouse fruiting vegetables (for example tomatoes, capsicums, aubergines, chili, but excluding cucurbits).

## 3. Assessment of the proposed modifications to the approval of Luna Privilege

### Assessments of risks associated with the proposed modifications

#### Risks to human health

- 3.1. The Committee noted that the risk assessment (contained in the amended science memorandum) indicated that without controls the proposed increase in maximum application rate to 600 mL of Luna Privilege / ha and use in greenhouses would result in risks above the level of concern for operators (chronic exposures) and re-entry workers (dermal exposure).
- 3.2. However, the predicted chronic risks to operators from mixing, loading and application of Luna Privilege at the proposed higher application rate are negligible, provided the operator wears gloves and coveralls as Personal Protective Equipment (PPE).
- 3.3. The risk from dermal exposure in greenhouses to re-entry workers can be mitigated with a Restricted Entry Interval (REI) of 13 days.
- 3.4. The Committee accepted the corrected assessment and determined that with the appropriate PPE and the setting of a REI by WorkSafe, the risks to human health are negligible.

## Risks to the environment

- 3.5. The applicant stated that increasing the maximum application rate to 600 mL/ha and increasing the number of applications to two would not pose any additional risks to the environment when used in accordance with appropriate controls.
- 3.6. A quantitative risk assessment to determine the potential risks posed by the higher application rate and number of applications and use of Luna Privilege in greenhouses was performed in order to assess the impacts associated with the proposed change of use parameters, and to identify additional control measures that would be required to mitigate any identified risks.
- 3.7. The physical containment associated with the use of Luna Privilege in greenhouses is a key factor in limiting the exposure to the aquatic and soil environments, and to terrestrial vertebrates such as birds. The EPA proposed that these risks could be mitigated by the implementation of a maximum application rate which will be restricted to use in greenhouses on crops not cultivated in soil.
- 3.8. The Committee considered these potential risks and noted that the implementation of the proposed controls, in particular, the restriction of the higher application rate to use in greenhouses for crops grown separated from the soil, will mitigate the risks to the environment outside of the application area.

## Cultural risk assessment

- 3.9. The applicant did not consult with Māori parties to identify potential risks to culturally significant species.
- 3.10. In their submission, Ngāi Tahu criticised the absence of consultation with Māori representatives and lack of information in the application form. In their presentation at the hearing, they reiterated these statements. The Committee concurred with these statements.
- 3.11. The potential effects of Luna Privilege on the relationship of Māori to the environment were also assessed by the EPA staff in accordance with sections 5(b), 6(d) and 8 of the Act.
- 3.12. The EPA's cultural risk assessment (CRA) considered potential risks and impacts on Māori interests including the relationship of Māori to the environment, culturally significant species and resources, and tikanga (customary values and practices) associated with these taonga. The CRA has identified cultural concerns in relation to human health and culturally significant species in particular taonga food

species. However, potential risks around these issues can be managed, therefore the application is not inconsistent with Māori cultural beliefs and environmental frameworks.

- 3.13. The Committee considered these potential risks and noted that the implementation of the proposed controls, in particular, the restriction of the use of Luna Privilege at the increased application rate to greenhouses will mitigate the risks.

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

- 3.14. The Committee agreed that the proposed modifications to the use of Luna Privilege do not pose risks to society, communities or the market economy.

### **New Zealand's international obligations**

- 3.15. The Committee agreed that the proposed modifications to the use of Luna Privilege will not affect any international obligations.

### **Assessment of benefits associated with the proposed modifications**

- 3.16. The applicant has indicated that increasing the maximum application rate and changing the application frequency and interval of Luna Privilege will allow the substance to be used on additional crops that are not currently listed on the label of the substance.
- 3.17. The applicant also noted that Luna Privilege will be an addition to the existing portfolio of products for controlling fungal diseases in these additional crops, thereby improving the choices available to farmers. The applicant also stated there are no fungicidal products registered for the control of botrytis in some of the greenhouse fruiting vegetables such as capsicums, aubergines and chili.
- 3.18. At the hearing, the applicant presented data on the efficacy of Luna Privilege against grey mould, brown rot and other diseases that reduce the quality and shelf-life of tomatoes and other greenhouse fruiting vegetables. The applicant also presented a comparison of the hazardous profiles of Luna Privilege with other products used to treat those diseases and showed that Luna Privilege has a lower hazard profile and lower application rate than some of the alternatives.
- 3.19. In their submission, Tomatoes NZ reiterated the value of Luna Privilege as a valuable tool for the control of botrytis on greenhouse tomatoes and noted the economic value of arable crops to New Zealand. At the hearing, they commented on its low hazard profile and compatibility with integrated pest management system.
- 3.20. In their submission, Vegetables New Zealand also reiterated the value of Luna Privilege as a valuable tool for the control of botrytis on greenhouse fruiting vegetables and noted the economic value of arable crops to New Zealand. At the hearing, they commented on the benefits of having additional crops on the label and providing growers application rate and timing directions to meet Maximum Residue Levels (MRL).

- 3.21. The Committee considered these proposed benefits and agreed that increasing the application rate of Luna Privilege could result in increased benefits to the market economy.

## 4. Proposed controls for Luna Privilege

- 4.1. The EPA staff recommended a series of proposed controls that would mitigate the additional risks posed by increasing the application rate and number of applications of Luna Privilege from 300 mL/ha to 600 mL/ha and one to two applications per year at an interval of at least seven days between applications.
- 4.2. These controls were evaluated by the Committee (in section 5) in accordance with the Hazardous Substances and New Organisms (Methodology) Order 1998 (“the Methodology”) to ascertain if the risks arising from the increased application rate could be found negligible, and if the benefits of any increase in application rate would outweigh any costs<sup>1</sup>.

### Prescribed controls

- 4.3. The hazard classifications of Luna Privilege determine a set of prescribed controls specified by the by the EPA Notices 2017. These form the basis of the suite of controls that are applied to Luna Privilege.

### Original section 77 and 77A controls

- 4.4. Section 77 of the Act allows the prescribed controls from the EPA Notices to be substituted, added and/or deleted where the adverse effects identified for a substance are different from those which would usually be associated with substances with the same hazard classification, the adverse effects cannot be identified for a substance because of scientific and technical uncertainty in the available information, or the benefits of the substance are retained without significantly increasing the adverse effects.
- 4.5. Section 77A of the Act also allows the EPA to add, vary, substitute, combine or delete controls if such changes are more effective or more cost-effective in terms of managing the use and risks of the substance, or are more likely to achieve their purpose than the prescribed controls.
- 4.6. As part of their presentation at the hearing, Ngāi Tahu expressed concern that the previous label did not include information about controls, such as prohibiting application onto water. The Committee noted that this is now a prescribed control under the EPA Labelling Notice.

### New section 77 and 77A controls

- 4.7. A maximum application rate for Luna Privilege was set under section 77A of the Act in the approval. In accordance with the purpose of this modified reassessment, the following maximum application rate controls were proposed by the EPA under section 77, changes are underlined:

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<sup>1</sup> Note that the proposed controls were amended as detailed in section 5; the finalised controls are given in Appendix A.

- When applied in greenhouses, the maximum application rate of this substance is 600 mL of substance / ha (equivalent to 300 g/ha of fluopyram).
- When applied in greenhouses, the substance must not be applied to the same area more than two times in any 365 day period, with a minimum interval between applications of seven days.

4.8. The following additional application restriction control was also proposed under section 77A: “When applied in greenhouses, the substance must not be applied to crops cultivated in the soil.”

## Modified section 77 and 77A controls

4.9. The following changes were also proposed by the EPA to differentiate the two use patterns and associated restrictions:

- When applied in field, the maximum application rate of this substance is 300 mL of substance / ha (equivalent to 150 g/ha of fluopyram).
- When applied in field, the substance must not be applied to the same area more than once in any 365 day period.

4.10. The Committee considered that the proposed controls are appropriate to manage the identified risks from the modified use proposal.

## Workplace controls

4.11. As a consequence of the updated risk assessment, the EPA staff’s provisional proposed controls (as detailed in the amended Evaluation and Review report), the controls on spray equipment to be used, PPE and limitation on the area that an operator could treat per day are no longer necessary. WorkSafe provided an updated evaluation of the risks in the workplace (presented in the amended Evaluation and Review report) and no concerns were raised.

4.12. At the hearing, Tomatoes NZ and Vegetables NZ commented on the non-amended risk assessment and indicated that the proposed controls were impractical; however, these comments are no longer relevant with the updated risk assessment that does not necessitate equipment restriction or limitation on the area an operator can treat per day.

4.13. The EPA recommends the use of gloves and coveralls to protect workers when using Luna Privilege.

4.14. WorkSafe will be setting a REI of 13 days when Luna Privilege is used in greenhouses.

## 5. Review of proposed controls for Luna Privilege

### Consideration of risks under proposed controls

5.1. The EPA staff’s proposed controls address the risks to human health and the environment by minimising exposure to workers and the environment outside of the treated area. The use of appropriate PPE and REI will reduce exposure to human health to below the acceptable level. The

Committee agrees that the higher application rate is restricted to greenhouse crops which are grown in containers to reduce exposure to the environment.

- 5.2. Availability and use of Luna Privilege also pose possible risks to Māori and their relationship to the environment through its potential to impact culturally significant and taonga species. The Committee was satisfied that the proposed controls will also mitigate these risks.

### Cost-effectiveness of controls

- 5.3. At the hearing, Tomatoes NZ and Vegetables NZ indicated that the controls proposed in the non-amended documents on spray equipment would not be commercially viable, however these controls are no longer proposed.
- 5.4. In accordance with clause 35 of the Methodology and sections 77 and 77A of the Act, the Committee considered the cost-effectiveness of the proposed controls. The Committee considered that the proposed controls are the most cost-effective in terms of their effect on the management, use and risks of the substance.

### Amendments to proposed controls by the Committee

- 5.5. The Committee reviewed the benefits associated with applying Luna Privilege at 600 mL/ha with two applications per year and determined that these were significant. They noted that the benefits of applying Luna Privilege at the requested application rate are increased relative to the maximum application rate set in the current approval as this allows use on new crops, and accordingly considered that the maximum application rate should be revised to 600 mL/ha, twice a year when Luna Privilege is used in greenhouses.
- 5.6. Having also reviewed the cost-effectiveness of the proposed controls, the Committee determined that the proposed controls needed to be amended to ensure they were most fit for purpose. The Committee intends that the following controls apply to Luna Sensation, replacing existing controls as necessary:

#### Application restrictions:

*The maximum application rate for this substance is 300 mL/ha (equivalent to 150 g/ha of fluopyram), with a maximum of one application in any 365 day period, except when the substance is used in greenhouses on crops separated from the soil.*

*The maximum application rate for this substance when used in greenhouses on crops separated from the soil is 600 mL/ha (equivalent to 300 g/ha of fluopyram), with a maximum of two applications in any 365 day period, and a minimum interval between applications of seven days.*

## 6. Proposed modifications to the approval of Luna Sensation

- 6.1. The suite of controls applied to Luna Sensation under approval HSR100998 includes the following control, which was applied under section 77A of the Act:

*The substance must not be applied at rates exceeding 0.15 L/ha per application, more than twice per year with an interval of at least 10 days between applications.*

- 6.2. The modified reassessment seeks to determine whether this control can be amended to allow a maximum application rate of 600 mL/ha (150 g fluopyram and 150 g trifloxystrobin/ha) per application, with a maximum of three applications per year at an interval of at least seven days between applications.
- 6.3. These changes would allow the use of Luna Sensation to be extended to stone fruits.

### Assessments of risks of Luna Sensation associated with the proposed modifications

#### Risks to human health

- 6.4. The Committee noted in the EPA staff assessment that the proposed increase in maximum application rate to 600 mL of Luna Sensation/ha and increase in number of applications results in increased risks to operators and re-entry workers.
- 6.5. The assessment showed that predicted chronic risks to operators from mixing, loading and application of Luna Sensation are negligible provided the operator wears gloves.
- 6.6. While the original risk assessment proposed a REI of 10 days; following review and assessment of an additional foliar residue study submitted by the applicant, the EPA staff revised the advice in regards to an appropriate REI. The revised EPA science memorandum<sup>2</sup> indicated that a REI of one day is sufficient to protect re-entry workers from dermal exposure in orchards.
- 6.7. The Committee agreed with this assessment and determined that with the appropriate PPE and the setting of a REI by WorkSafe, the risks are negligible.

#### Risks to the environment

- 6.8. The applicant submitted that increasing the maximum application rate to 600 mL/ha and increasing the number of applications to three would not pose any additional risks to the environment when used in accordance with appropriate controls.
- 6.9. A quantitative risk assessment to determine the potential risks posed by the higher application rate and number of applications and use of Luna Sensation on stone fruits was performed in order to identify additional control measures that would be required to mitigate any risks.

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<sup>2</sup> published on 9 August 2018

- 6.10. The environmental risk assessment conducted by the EPA calculated that applying Luna Sensation at the proposed rate of 600 mL/ha poses risks to aquatic organisms. The EPA staff proposed that these risks could be mitigated by the implementation of a buffer zone.
- 6.11. The Committee determined that applying a buffer zone, in conjunction with appropriate restrictions on application method to minimise spray drift is an appropriate mechanism to mitigate the risks to aquatic organisms.
- 6.12. Given that the substance has the potential to adversely affect insects used in Integrated Pest Management (IPM), the EPA staff consider that the following label statement should be added to be consistent with the warnings that apply to the substance in Australia: "Luna Sensation may have an adverse effect on predatory bugs (*Orius* spp.) if used where IPM is practised. Safety to ladybirds, syrphid flies and lacewings has not been evaluated."
- 6.13. The Committee considered the proposal to set a label control to protect beneficial arthropods is an appropriate mechanism to mitigate the risks to non-target terrestrial invertebrates.

### **Cultural risk assessment**

- 6.14. The applicant did not consult with Māori parties to identify potential risks to culturally significant species.
- 6.15. In their submission, Ngāi Tahu criticised the absence of consultation with Māori representatives and lack of information in the application form. In their presentation at the hearing, they reiterated these statements. The Committee concurred with these statements.
- 6.16. The EPA's cultural risk assessment (CRA) considered potential risks and impacts on Māori interests including the relationship of Māori to the environment, culturally significant species and resources, and tikanga (customary values and practices) associated with these taonga. The CRA has identified cultural concerns in relation to human health and culturally significant species in particular taonga food species. However, potential risks around these issues can be managed, therefore the application is not inconsistent with Māori cultural beliefs and environmental frameworks.

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

- 6.17. The Committee agreed that the proposed modifications to the use of Luna Sensation do not pose risks to society, communities or the market economy.

### **New Zealand's international obligations**

- 6.18. The Committee agreed that the proposed modifications to the use of Luna Sensation will not affect any international obligations.

## Assessment of benefits of Luna Sensation associated with the proposed modifications

- 6.19. The applicant has indicated that increasing the maximum application rate and changing the application frequency and interval of Luna Sensation will allow the substance to be used on additional crops that are not currently listed on the label of the substance.
- 6.20. The applicant also noted that these will be an addition to the existing portfolio of products for controlling fungal diseases in these additional crops, thereby improving the choices available to farmers.
- 6.21. At the hearing, the applicant presented data on the efficacy of Luna Sensation against brown rot and other diseases that reduce the quality and shelf-life of stone fruits. The applicant also showed that Luna Sensation has a lower hazard profile or lower application rate than some of the alternatives to treat those diseases.
- 6.22. In their submission, Summerfruit NZ reiterated the value of Luna Sensation as a valuable tool for the control of brown rot on stone fruits and noted the economic value of arable crops to New Zealand. At the hearing they highlighted that the current products used have resistance issues and that they consider that Luna Sensation could be used with their SummerGreen IPM program. They also stated that the application on stone fruits requires a higher application rate than what is currently approved.
- 6.23. The Committee considered these proposed benefits and agreed that increasing the application rate of Luna Sensation could result in increased benefits to the market economy.

## 7. Proposed controls for Luna Sensation

- 7.1. In the Evaluation and Review report, the EPA staff recommended a series of proposed controls that would mitigate the additional risks posed by increasing the application rate and number of applications of Luna Sensation from 150 mL/ha to 600 mL/ha and from two to three applications per year, with an interval of at least seven days between applications.
- 7.2. These controls were evaluated by the Committee (in section 8) in accordance with the Hazardous Substances and New Organisms (Methodology) Order 1998 (“the Methodology”) to ascertain if the risks arising from the increased application rate could be found negligible, and if the benefits of any increase in application rate would outweigh any costs<sup>3</sup>.

### Prescribed controls

- 7.3. The hazard classifications of Luna Sensation determine a set of prescribed controls specified by the EPA Notices 2017. These form the basis of the suite of controls that are applied to Luna Sensation.

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<sup>3</sup> Note that the proposed controls were amended as detailed in section 5; the finalised controls are given in Appendix A.

## Original section 77 and 77A controls

- 7.4. Section 77 of the Act allows the prescribed controls from the EPA Notices to be substituted, added and/or deleted where the adverse effects identified for a substance are different from those which would usually be associated with substances with the same hazard classification, the adverse effects cannot be identified for a substance because of the scientific and technical uncertainty in the available information, or the benefits of the substance are retained without significantly increasing the adverse effects.
- 7.5. Section 77A of the Act also allows the EPA to add, vary, substitute, combine or delete controls if such changes are more effective or more cost-effective in terms of managing the use and risks of the substance, or are more likely to achieve their purpose than the prescribed controls.
- 7.6. As part of their presentation at the hearing, Ngāi Tahu expressed concern that the previous label did not include information about controls, such as prohibiting application onto water. The Committee noted that this is now a prescribed control under the EPA Labelling Notice.

## New section 77 and 77A controls

- 7.7. A maximum application rate for Luna Sensation was set under section 77A of the Act in the initial approval. In accordance with the purpose of this modified reassessment, the following maximum application rate controls were proposed by EPA staff under section 77; changes are underlined:
- When applied on stone fruits, the substance must not be applied at rates exceeding 600 mL /ha per application, more than three times in any 365 day period with an interval of at least seven days between applications
- 7.8. The following additional application restriction controls were also proposed by EPA staff to mitigate risks to aquatic organisms from spray drift:
- When applied on stone fruits, the substance must not be applied when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site.
  - When applied on stone fruits, the substance must not be applied within 15 metres of a downwind waterbody.
- 7.9. The following additional label control was proposed by EPA staff to mitigate risks to beneficial arthropods. The following statement, or words to the same effect, must be present on the label: “Luna Sensation may have an adverse effect on predatory bugs (Orius spp.) if used where IPM is practised. Safety to ladybirds, syrphid flies and lacewings has not been evaluated”.

## Modified section 77 and 77A controls

- 7.10. The EPA staff also proposed the following changes in order to differentiate the two use patterns and associated restrictions:

- *When applied on grapes, the substance must not be applied at rates exceeding 150 mL /ha per application, more than twice per year with an interval of at least ten days between applications*

7.11. The Committee considered that the proposed controls are appropriate to manage the identified risks from the modified use proposal.

## Workplace controls

7.12. The assessment of the applicant's additional information reduced the EPA staff's proposed REI from ten days to one day.<sup>4</sup>

7.13. After the hearing and publication of the corrected science memorandum for Luna Sensation, Summerfruit NZ submitted in support of the one day REI for Luna Sensation when used on stone fruits.

7.14. WorkSafe will be setting a REI of one day when Luna Sensation is used on stone fruits.

7.15. The EPA recommends the use of gloves to protect workers when using Luna Sensation.

## 8. Review of proposed controls for Luna Sensation

### Consideration of risks under proposed controls

8.1. The Committee consider that the proposed controls address the risks to human health and the environment by minimising exposure to workers and the environment outside of the treated area. The application of a buffer zone for Luna Sensation when used on stone fruits will reduce exposure to the environment. The additional label statement will alert users of risks to non-target terrestrial invertebrates.

8.2. Luna Sensation also poses possible risks to Māori and their relationship to the environment through its potential to impact culturally significant and taonga species. The Committee was satisfied that the proposed controls will also mitigate these risks.

### Cost-effectiveness of controls

8.3. In accordance with clause 35 of the Methodology and sections 77 and 77A of the Act, the Committee considered the cost-effectiveness of the proposed controls. The Committee considered that the proposed controls are the most cost-effective in terms of their effect on the management, use and risks of the substance.

### Amendments to proposed controls by the Committee

8.4. The Committee reviewed the benefits associated with applying Luna Sensation at 600 mL/ha with three applications per year and determined that these were significant. They noted that the benefits of

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<sup>4</sup> refer to amended Evaluation and Review report.

applying Luna Sensation at the requested application rate are increased relative to the maximum application rate set in the current approval as this allows use on new crops, and accordingly considered that the maximum application rate should be revised to 600 mL/ha, three times a year when Luna Sensation is used on stone fruits.

- 8.5. Having also reviewed the cost-effectiveness of the proposed controls, the Committee determined that the proposed controls needed to be amended to ensure they were most fit for purpose. The Committee intends that the following controls apply to Luna Sensation, replacing existing controls as necessary:

#### Application restrictions:

- *The maximum application rate for this substance is 150 mL/ha per application, with a maximum of two applications in any 365 day period and an interval of at least ten days between applications, except when the substance is used on stone fruits.*
- *The maximum application rate for this substance when applied on stone fruits is 600 mL/ha per application, with a maximum of three applications in any 365 day period and an interval of at least seven days between applications.*
- *When applied at rates greater than 150 mL/ha, the substance must not be applied when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site.*

#### Buffer zones

- *When applied at rates greater than 150 mL/ha, the substance must not be applied within 15 metres of a downwind water body.*

#### Label

- The following statement, or words to the same effect, must be present on the label: *“Luna Sensation may have an adverse effect on predatory bugs (Orius spp.) if used where IPM is practised. Safety to ladybirds, syrphid flies and lacewings has not been evaluated”.*

## 9. Consideration and decision

- 9.1. Pursuant to section 63A of the Act, the Committee considered this application to amend the approval of two hazardous substances. In doing so, the Committee applied the relevant sections of the Act and clauses of the Hazardous Substances and New Organisms (Methodology) Order 1998.
- 9.2. The Committee considered that, having taken the modified use pattern into account, the benefits associated with the availability and use of Luna Privilege outweigh the negligible risks.
- 9.3. Therefore, the Committee approved the increase of the maximum application rate of Luna Privilege, to allow application at up to 600 mL/ha, twice per year, with a minimum interval of seven days between

applications in accordance with clause 26, assigning the modified suite of controls listed in Appendix A to Luna Privilege.

- 9.4. The Committee considered that having taken the modified use pattern into account, the benefits associated with the availability and use of Luna Sensation outweigh the negligible risks.
- 9.5. Therefore, the Committee approved the increase of the maximum application rate of Luna Sensation, to allow application at up to 600 mL/ha, three times per year, with a minimum interval of seven days between applications in accordance with clause 26, assigning the modified suite of controls listed in Appendix B to Luna Sensation.



Environmental  
Protection Authority  
Te Whiriwhiri Rauhi Taiao

**Dr Ngairé Phillips**

**Date: 5 November 2018**

Chair, Decision Making Committee  
Environmental Protection Authority

HSR100746 and HSR100998

## Appendix A: Controls applying to Luna Privilege

The following are the current controls for Luna Privilege, including the proposed new controls which are highlighted in blue. Minor technical changes to current controls are highlighted in green. The controls are updated to the EPA Notices and HSW (HS) regulations.

Control code	Notice	Control description	Additional information
LAB	EPA Labelling Notice 2017	<a href="#">Requirements for labelling of hazardous substances</a>	
PKG	EPA Packaging Notice 2017	<a href="#">Requirements for packaging of hazardous substances</a>	
SDS	EPA Safety Data Sheet Notice 2017	<a href="#">Requirements for safety data sheets for hazardous substances</a>	A WES value has been set for propylene glycol
DIS	EPA Disposal Notice 2017	<a href="#">Requirements for disposal of hazardous substances</a>	
HPC-1	EPA Hazardous Property Controls Notice 2017 Part 1	<a href="#">Hazardous Property Controls preliminary provisions</a>	
HPC-3	EPA Hazardous Property Controls Notice 2017 Part 3	<a href="#">Hazardous substances in a place other than a workplace</a>	
HPC-4A	EPA Hazardous Property Controls Notice 2017 Part 4A	<a href="#">Site and storage controls for class 9 substances</a>	
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B	<a href="#">Use of class 9 substances</a>	The additional water control in the original decision is now a prescribed control in this notice (Clause 52). No EEL is set for the substance (Clause 49).

## HSNO Additional Controls and Modifications to Controls (highlighted)

Code	HSNO Act	Control
Application restrictions	Section 77	<p>The maximum application rate for this substance is 300 mL/ha (equivalent to 150 g/ha of fluopyram), with a maximum of one application in any 365 day period, except when the substance is used in greenhouses on crops separated from the soil.</p> <p>The maximum application rate for this substance when used in greenhouses on crops separated from the soil is 600 mL/ha (equivalent to 300 g/ha of</p>

		fluopyram), with a maximum of two applications in any 365 day period, and a minimum interval between applications of seven days.
Application method	Section 77A	This substance must be applied via ground-based methods only.

## 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	Additional information
HSW2-1	Reg 2.1 - 2.4	<a href="#">Workplace labelling of hazardous substance containers</a>	
HSW2-2	Reg 2.5 - 2.10	<a href="#">Signage</a>	
HSW2-3	Reg 2.11	<a href="#">Safety data sheets</a>	
HSW2-4	Reg 2.12 - 12.14	<a href="#">Packaging</a>	
HSW3-1	Reg 3.1	<a href="#">Inventory</a>	
HSW3-2	Reg 3.2 - 3.3	<a href="#">Managing risks associated with hazardous substances</a>	
HSW4-2	Reg 4.5 - 4.6	<a href="#">Information, instruction, training and supervision</a>	
HSW13-2	Reg 13.7	<a href="#">Duty of PCBU who directs work using class 6, 8.1, 8.2, or 8.3 substances to ensure equipment is appropriate</a>	
HSW13-3	Reg 13.8	<a href="#">Duty of PCBU who directs work using class 6 and 8 substances to ensure personal protective equipment used</a>	
HSW13-8	Reg 13.17	<a href="#">Prohibition on use of substance in excess of tolerable exposure limit</a>	
HSW13-9	Reg 13.18	<a href="#">Duty of PCBU to ensure prescribed exposure standards for class 6 substances not exceeded</a>	
HSW13-12	Reg 13.23 – 13.25	<a href="#">Restricted entry intervals</a>	The restricted entry interval is 13 days when Luna Privilege is used in greenhouses.
HSW16-1	Part 16	<a href="#">Requirements for tank wagons and transportable containers</a>	

HSW17-1

Part 17

[Requirements for surface containers](#)

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## Appendix B: Controls for Luna Sensation

The following are the current controls for Luna Sensation (HSR100998), including the proposed new controls which are highlighted in blue. Minor technical changes to current controls are highlighted in green.

Control code	Notice	Control description	Additional information
LAB	EPA Labelling Notice 2017	<a href="#">Requirements for labelling of hazardous substances</a>	
PKG	EPA Packaging Notice 2017	<a href="#">Requirements for packaging of hazardous substances</a>	
SDS	EPA Safety Data Sheet Notice 2017	<a href="#">Requirements for safety data sheets for hazardous substances</a>	A WES value has been set for propylene glycol
DIS	EPA Disposal Notice 2017	<a href="#">Requirements for disposal of hazardous substances</a>	
HPC-1	EPA Hazardous Property Controls Notice 2017 Part 1	<a href="#">Hazardous Property Controls preliminary provisions</a>	
HPC-3	EPA Hazardous Property Controls Notice 2017 Part 3	<a href="#">Hazardous substances in a place other than a workplace</a>	
HPC-4A	EPA Hazardous Property Controls Notice 2017 Part 4A	<a href="#">Site and storage controls for class 9 substances</a>	
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B	<a href="#">Use of class 9 substances</a>	The additional water control in the original decision is now a prescribed control in this notice (Clause 52). No EEL is set for the substance (Clause 49).
HPC-4C	EPA Hazardous Property Controls Notice 2017 Part 4C	<a href="#">Qualifications required for application of class 9 pesticides</a>	

## HSNO Additional Controls and Modifications to Controls

Code	HSNO Act	Control
Application restrictions	Section 77	The maximum application rate for this substance is 150 mL/ha per application, with a maximum of two applications in any 365 day period and an interval of at least ten days between applications, except when the substance is used on stone fruits.

		The maximum application rate for this substance when applied on stone fruits is 600 mL/ha per application, with a maximum of three applications in any 365 day period and an interval of at least seven days between applications
Application method	Section 77A	This substance must be applied via ground-based methods only. When applied at rates greater than 150 mL/ha, the substance must not be applied when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site.
Buffer zone	Section 77A	When applied at rates greater than 150 mL/ha, the substance must not be applied within 15 metres of a downwind water body.
Label	Section 77	The following statement, or words to the same effect, must be present on the label: "Luna Sensation may have an adverse effect on predatory bugs (Orius spp.) if used where IPM is practised. Safety to ladybirds, syrphid flies and lacewings has not been evaluated".

## 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	Additional information
HSW2-1	Reg 2.1 - 2.4	<a href="#">Workplace labelling of hazardous substance containers</a>	
HSW2-2	Reg 2.5 - 2.10	<a href="#">Signage</a>	
HSW2-3	Reg 2.11	<a href="#">Safety data sheets</a>	
HSW2-4	Reg 2.12 - 12.14	<a href="#">Packaging</a>	
HSW3-1	Reg 3.1	<a href="#">Inventory</a>	
HSW3-2	Reg 3.2 - 3.3	<a href="#">Managing risks associated with hazardous substances</a>	
HSW4-2	Reg 4.5 - 4.6	<a href="#">Information, instruction, training and supervision</a>	
HSW5-2	Reg 5.6 - 5.13	<a href="#">Emergency response plans</a>	
HSW13-2	Reg 13.7	<a href="#">Duty of PCBU who directs work using class 6, 8.1, 8.2, or 8.3 substances to ensure equipment is appropriate</a>	
HSW13-3	Reg 13.8	<a href="#">Duty of PCBU who directs work using class 6 and 8 substances to ensure personal protective equipment used</a>	

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HSW13-8	Reg 13.17	<a href="#">Prohibition on use of substance in excess of tolerable exposure limit</a>	
HSW13-9	Reg 13.18	<a href="#">Duty of PCBU to ensure prescribed exposure standards for class 6 substances not exceeded</a>	
HSW13-12	Reg 13.23 – 13.25	<a href="#">Restricted entry intervals</a>	The restricted entry interval is 1 day when Luna Sensation is used on stone fruits.
HSW13-14	Reg 13.30 - 33	<a href="#">Secondary containment requirements for class 6 and 8 pooling substances</a>	
HSW16-1	Part 16	<a href="#">Requirements for tank wagons and transportable containers</a>	
HSW17-1	Part 17	<a href="#">Requirements for surface containers</a>	

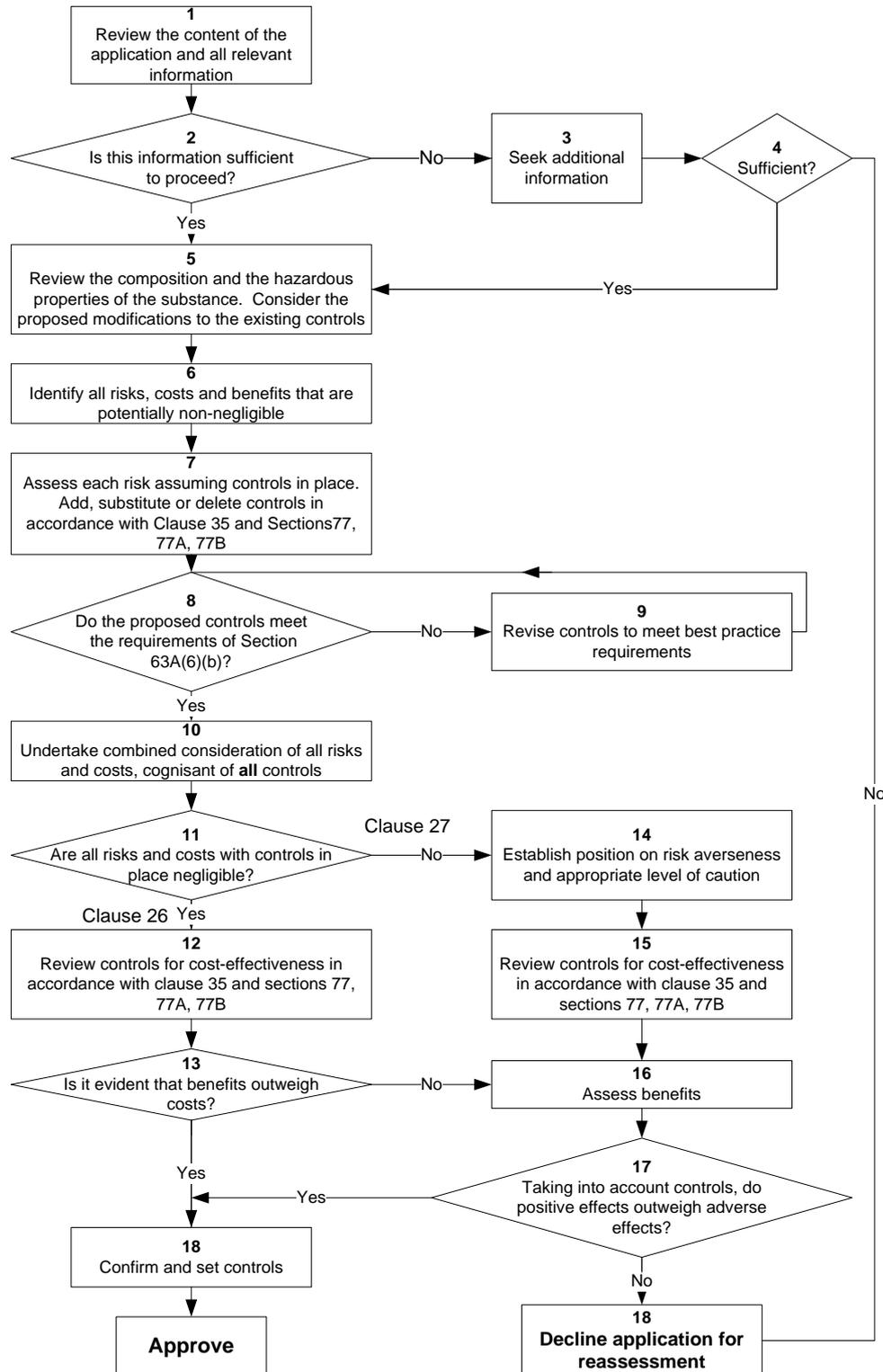
## Appendix C: Decision Path

### 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 63 of the HSNO Act.

**Figure 1A 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 1A Explanatory Notes

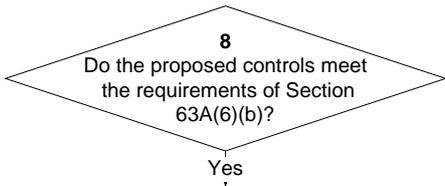
Item 1:	<p><b>Review the content of the application and all relevant information</b></p> <p>Review the application, the E&amp;R Report, and information received from experts and that provided in submissions (where relevant) in terms of section 28(2) of the Act and clauses 8, 15, 16 and 20 of the Methodology.</p> <p>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.</p>
Item 2:	<p><b>Is this information sufficient to proceed?</b></p> <p>Review the information and determine whether or not there is sufficient information available to make a decision.</p>
Item 3:	<p><b>(if 'no') Seek additional information</b></p> <p>If there is not sufficient information then additional information may need to be sought under section 52 or 58 of the Act.</p> <p>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.</p>
Item 4	<p><b>Sufficient?</b></p> <p>When additional information has been sought, has this been provided, and is there now sufficient information available to make a decision?</p> <p>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).</p>
Item 5:	<p><b>(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</b></p> <p>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.</p> <p>Consider the proposed modifications to the existing controls.</p>
Item 6:	<p><b>Identify all risks, costs and benefits that are potentially non-negligible<sup>5</sup></b></p> <p>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.</p> <p>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.</p>

<sup>5</sup> 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.

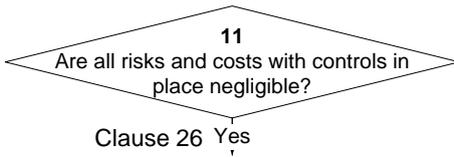
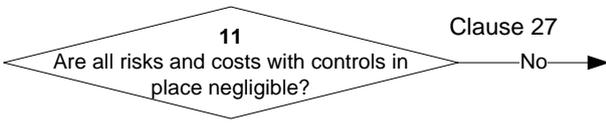
	<p>Examples of costs that cannot be considered as risks are one-off direct financial costs incurred by applicants that cannot be considered as 'sunk' costs (see footnote 1). Where such costs arise they will be considered in the same way as risks, but their likelihood of occurrence will be more certain.</p> <p>Identification is a two-step process that scopes the range of possible effects (risks, costs and benefits).</p>
	<p><b>Step 1:</b></p> <p>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<sup>6</sup>. 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)).</p> <p>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).</p> <p>Consider short term and long term effects.</p> <p>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.</p> <p><b>Step 2:</b></p> <p>Document those risks, costs and benefits that can be readily concluded to be negligible<sup>7</sup>, and eliminate them from further consideration.</p> <p>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.</p>
Item 7:	<p><b>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.</b></p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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</p>

<sup>6</sup> 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.

<sup>7</sup> 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."

	<p>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)).</p> <p>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.</p> <p>See EPA report 'Approach to Risk' for further guidance<sup>8</sup>.</p> <p>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.</p> <p>If changes are made to the controls at this stage then the approach to uncertainty and the approach to risk must be revisited.</p>
Item 8:	<p><b>Do the proposed controls meet the requirements of Section 63A(6)(b)?</b></p> <p>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.</p>
Item 9:	<p><b>(if 'no' from item 8) Revise controls to meet best practice requirements</b></p> <p>If the controls do not meet the best international practice criteria, then modify the controls so that they do meet them.</p>
Item 10:	<div style="text-align: center;">  <p>8 Do the proposed controls meet the requirements of Section 63A(6)(b)? Yes</p> </div> <p><b>(if 'yes' from item 8) Undertake combined consideration of all risks and costs, cognisant of proposed controls</b></p> <p>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.</p>
Item 11:	<p><b>Are all risks and costs with controls in place negligible?</b></p> <p>Looking at individual risks in the context of the 'basket' of risks, consider whether any of the residual risks (costs) are negligible.</p>

<sup>8</sup> <http://www.epa.govt.nz/Publications/Approach-to-Risk.pdf>

Item 12:	<div style="text-align: center;">  <p>11 Are all risks and costs with controls in place negligible? Clause 26 Yes</p> </div> <p><b>(if 'yes' from item 11) Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B</b></p> <p>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.</p>
Item 13:	<p><b>Is it evident that benefits outweigh costs?</b></p> <p>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.</p> <p>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.</p> <p>Consider whether there are any non-negligible external costs that are not associated with risks.</p> <p>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<sup>9</sup>.</p> <p>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.</p> <p>However, if this is not the case and there are external non-negligible costs then all benefits need to be assessed (via item 16).</p>
Item 14:	<div style="text-align: center;">  <p>11 Are all risks and costs with controls in place negligible? Clause 27 No</p> </div> <p><b>(if 'no' from item 10) Establish HSNO decision maker's position on risk averseness and appropriate level of caution</b></p> <p>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).</p>

<sup>9</sup>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'

Item 15:	<p><b>Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B</b></p> <p>This constitutes a decision made under clause 27 of the Methodology (taken in sequence from items 10, 13, 14 and 15).</p> <p>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.</p>
Item 16:	<p><b>(if 'no' from item 13, or in sequence from item 15) Assess benefits</b></p> <p>Assess benefits or positive effects in terms of clause 13 of the Methodology.</p> <p>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.</p> <p>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<sup>10</sup>. 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.</p> <p>As for risks and costs the assessment is carried out with the default controls in place.</p>
Item 17:	<p><b>Taking into account controls, do positive effects outweigh adverse effects?</b></p> <p>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.</p> <p>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.</p> <p>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.</p>
Item 18:	<p><b>(if 'no' from item 4 or item 17) Decline application for reassessment</b></p>

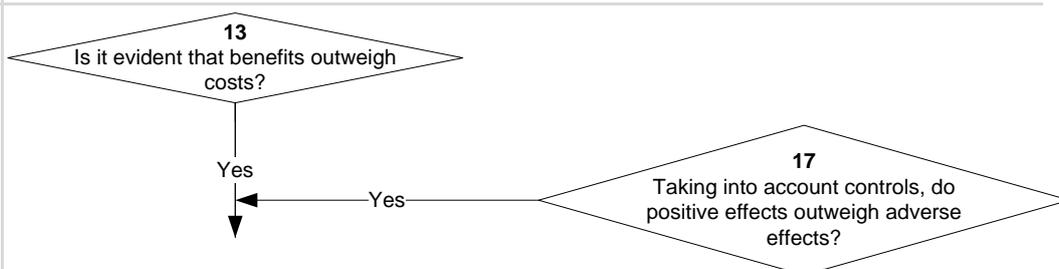
<sup>10</sup> Clause 13 of the Methodology

(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.