Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

1 DECEMBER 2020

Summary

Substance	Soleto
Application code	APP203925
Application type	To import or manufacture for release any hazardous substance under Section 28 of the Hazardous Substances and New Organisms Act 1996 (“the Act”)
Applicant	Belchim Crop Protection NV/SA
Purpose of the application	To import or manufacture Soleto for release
Considered by	A Decision-Making Committee of the Environmental Protection Authority (“the Committee”): Dr Louise Malone (Chair) Dr Kerry Laing
Decision	**Approved with controls**
Approval code	**HSR101457**
Hazard classifications	6.1E (oral), 6.7B, 6.9B (oral), 9.1A, 9.2A

Application dates	
Date application formally received	13 March 2020
Submission period	24 August 2020 – 5 October 2020
Consideration date	5 November 2020 - 11 November 2020
Date decision signed	1 December 2020

1. Application context

Background

1.1. The applicant, Belchim Crop Protection NV/SA, submitted an application on 18 September 2019 to import or manufacture[1] for release Soleto into New Zealand. It was given the application number APP203925 and was formally received on 13 March 2020 as a notified Category C application.

1.2. Soleto is a suspension concentrate containing 500 g/L metobromuron as the active ingredient.

1.3. Metobromuron is a new active ingredient to New Zealand, however it is approved in Europe.

1.4. Soleto is intended to be used as a herbicide for the control of weeds in potato crops. The applicant has proposed an application rate of 1.5 to 2 kg metobromuron/ha (equivalent to 3 to 4 L/ha Soleto), with one application per crop cycle. The applicant sought to have Soleto approved for ground-based application methods only.

Process, consultation and notification

1.5. The application was formally received on 13 March 2020 under section 28 of the Act.

Notification to government departments

1.6. The following government departments were notified of the application on 24 August 2020: 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 advised of the application and notified of the consultation period. No comments or submissions on the application were received from these parties.

1.7. WorkSafe New Zealand ("WorkSafe") is the agency responsible for overseeing the Health and Safety at Work Act 2015 (HSW Act) and the Health and Safety at Work (Hazardous Substances) Regulations 2017 (HSW (HS) Regulations). Advice was sought from WorkSafe on whether the HSW requirements are adequate to manage the risks associated with the use of this substance in the workplace.

1.8. WorkSafe noted that Soleto contains a new herbicide active ingredient, expecting that it may not have significant human health hazards. WorkSafe noted that a recent review of the new herbicide active ingredients approved in New Zealand over a five year period showed that three of six new herbicide active ingredients had no human health hazards, with one classified as a skin sensitiser and only two having chronic health hazards. WorkSafe noted that metobromuron has been classified by the EPA as a 6.7B (suspected human carcinogen) and 6.9B (target organ toxicity). WorkSafe identified that the Person Conducting a Business or Undertaking (PCBU) may not have gone so far as reasonably practical to ensure Soleto was without risk, and so advised that the duties under sections 39 to 42 of the HSW Act may not have been met for this substance. However, WorkSafe did not propose setting

[1] Manufacture, as defined in the Hazardous Substances (Packaging) Notice 2017, includes repacking or relabelling. The applicant has stated that manufacturing (production of Soleto) will occur overseas and that relabelling of the formulated substance will occur in New Zealand in a dedicated chemical facility.

any additional requirements for Soleto. The full advice is available in a separate report provided by WorkSafe.

Public consultation

1.9. The application was publicly notified in accordance with section 53 of the Act, and public submissions were sought from 24 August 2020 to 5 October 2020. The EPA did not receive any submissions on the application.

Timeframe waiver

1.10. The timeframe for the opening of the public consultation was waived on 13 March 2020 under section 59 of the Act to allow preparation of the draft Science Memorandum, which contains the EPA risk assessment, in order to allow any potential submitter to have this document at their disposal for making an informed submission.

Submissions

1.11. No submissions were received.

Hearing

1.12. As no submissions were received, no hearing was held.

Legislative criteria for the application

1.13. The application was considered in accordance with section 29 of the Act, taking into account other relevant sections of the Act, the EPA Notices, the HSW Act and HSW (HS) Regulations and the Hazardous Substances and New Organisms (Methodology) Order 1998.

2. The EPA Staff Report

2.1. The Staff Report is the EPA review of the application and available information. It provides information to assist the Committee's decision-making process.

2.2. The EPA identified the classifications and properties of the active ingredient, metobromuron, in Soleto based on toxicological and ecotoxicological studies conducted with this active ingredient. The EPA then identified the classifications of the substance Soleto, which are based on formulation data, the composition of the substance, and the properties of its components.

2.3. The EPA conducted quantitative human health and environmental risk assessments. These assessments considered the exposure and subsequent effects on people and the environment throughout the import and use phases of the life cycle of the substance. Based on all the available information, the EPA assessed the potential risks the substance may pose to the environment, human health, the relationship of Māori to the environment, society, community and to the market economy.

2.4. The EPA also considered whether there were benefits associated with the use of the substance.

2.5. The EPA identified a suite of prescribed controls based on the hazard classifications of Soleto and considered variations to these controls, and the addition of extra controls, in accordance with sections 77 and 77A of the Act.

2.6. The EPA Staff Report (dated November 2020) concluded that there was sufficient information available to assess the application to import or manufacture Soleto for release. The Staff Report also concluded that, with the proposed controls in place, the risks to human health and the environment from the importation, manufacture and use of Soleto would be negligible, except for non-threatened species of soil mites and Collembola for which a low risk has been identified; and that the use of Soleto would provide some benefits to farmers.

2.7. The EPA Staff Report concluded that with the proposed controls in place, the benefits of the substance would outweigh the risks of the substance.

3. Consideration

3.1. The application was considered by the Committee on 11 November 2020, following the decision pathway (available in Appendix B).

3.2. The following information was considered by the Committee:

- the application form and its confidential appendices, including about 130 studies
- the Science Memorandum
- the Staff Report
- the WorkSafe assessment report
- the Cultural Risk Assessment

3.3. The Committee considered that it had received sufficient information to proceed with its consideration of the application. Further comments on different aspects of this information can be found in the following sections.

Hazard classifications

3.4. The Committee adopted the hazard classifications for Soleto as recommended in the Science Memorandum, based on the information provided by the applicant and on other available information as documented in the Science Memorandum. The EPA classifications differed slightly from those proposed by the applicant (see Table 1).

Table 1: Hazard classifications of Soleto

Hazard	Applicant classification	EPA classification
Acute toxicity (oral)	**No**	**6.1E**
Carcinogenicity	6.7B	6.7B
Target organ or systemic toxicity	6.9B	6.9B (oral)
Aquatic ecotoxicity	9.1A	9.1A
Soil ecotoxicity	9.2A	9.2A

Risk assessment

3.5. The Committee took into account the EPA risk assessment for Soleto as detailed in the Science Memorandum. The key points are summarised below.

3.6. The risk assessment took into account the import and use phases of the life cycle of the substance, including import, packaging, transport, storage, use and disposal.

3.7. The overall risk and benefit assessment:

- considered the risks posed by Soleto;
- determined whether the risks are outweighed by the benefits;
- determined whether any variations or additions to the prescribed controls are required to manage the risks of this substance, and identified controls that may not be applicable or necessary that can, therefore, be deleted.

Risks during importation, manufacture, transportation, storage and disposal

3.8. The applicant intends to import Soleto packaged ready for sale. The risks associated with the importation, transportation, storage and disposal of Soleto were considered by the Committee based on the EPA risk assessment.

3.9. The Committee considered that adherence to the proposed controls and other legislative requirements would ensure that the level of risk to human health and the environment from importation, transportation, storage and disposal of Soleto would be negligible. These include the Hazardous Substances Notices regarding packaging, identification, emergency management and disposal of hazardous substances, the Land Transport Rule 45001, Civil Aviation Act 1990, Maritime Transport Act 1994 and New Zealand's HSW requirements.

Assessment of risks to human health

3.10. The Committee noted that the quantitative risk assessment determined that risks to operators during mixing, loading and application of Soleto for each use pattern were below the level of concern with the use of personal protective equipment (PPE).

3.11. The Committee noted that the EPA assessment determined that the risks to re-entry workers and bystanders were below the level of concern.

3.12. The Committee noted that WorkSafe assessed the available information for Soleto and considered that compliance with the HSW (HS) and HSW (General Risk and Workplace Management) Regulations would be adequate to reduce the risks associated with the use of this substance in the workplace.

Assessment of risks to the environment

3.13. The Committee noted that the EPA had conducted a quantitative risk assessment. The risk assessment considered the effect of the proposed use of Soleto on target and non-target organisms in the environment.

Aquatic organisms

3.14. The Committee noted that the EPA assessment showed non-acceptable risks to aquatic organisms. They also noted that to mitigate the risks from spray drift and runoff, additional controls requiring a maximum application rate, ground-based application methods, wind speed limits, a medium droplet quality spray and a 5 m buffer zone for any waterbody as proposed by the EPA would be necessary.

Sediment-dwelling organisms

3.15. The Committee noted that risks to sediment-dwelling organisms from the proposed use of Soleto were identified by the EPA as being below the level of concern.

Groundwater

3.16. The Committee noted that risks associated with the drinking of groundwater were identified by the EPA as being below the level of concern.

Soil organisms

3.17. The Committee noted that risks to threatened and non-threatened earthworms from the proposed use of Soleto were identified by the EPA as being below the level of concern.

3.18. The Committee noted that a chronic risk above the level of concern was identified for non-threatened species of soil mites and Collembola in-field. They noted that this risk was considered by the EPA to be low.

3.19. The Committee noted that risks to soil micro-organisms from the proposed use of Soleto were identified by the EPA as being below the level of concern.

Non-target plants

3.20. The Committee noted that the EPA assessment found that risks to non-target plants from the proposed use of Soleto were non-negligible. They also noted that additional controls, including a 5 m buffer zone, wind speed limits and a label statement requirement to check whether threatened plants are adjacent to the spray site, were proposed by the EPA.

Birds

3.21. The Committee noted that the chronic risks to birds from the proposed use of Soleto were identified by the EPA as being non-negligible. However, after further refinement, considering the conservatism of the chronic toxicity endpoint, the possibility that birds will forage in other (non-treated) areas and the limited availability of contaminated food, these risks were likely to be below the level of concern, therefore, the Committee did not propose any conditional controls.

Pollinators and non-target arthropods

3.22. The Committee noted that risks to pollinators from the proposed use of Soleto were identified by the EPA as being below the level of concern.

3.23. The Committee noted that the EPA assessment found that the risks to non-target arthropods from the proposed use of Soleto may be non-negligible, and that the EPA had therefore proposed an additional label statement to ensure mechanical removal of weeds, remaining crop and seeds before application and that the substance should only be applied after planting and before crop emergence.

Assessment of risks to Māori and their relationship to the environment

3.24. The Committee noted that the EPA assessed the potential effects on the relationship of Māori to the environment in accordance with sections 5(b), 6(d) and 8 of the Act. This included an assessment of the potential impacts of Soleto on kaitiakitanga, and fulfilment of Treaty of Waitangi obligations.

3.25. Based on the Māori perspective report and other information provided to the Committee by the applicant, the Committee considered that with the proposed controls in place, the impact of approval of use of Soleto on the relationship of Māori to the environment would be negligible, and likely to be consistent with the principles of the Treaty of Waitangi.

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

3.26. The Committee considered that the overall level of risk to society, the community and the market economy after taking into account the controls would be negligible.

New Zealand's international obligations

3.27. The Committee noted no international obligations have been identified that may be impacted by the approval of Soleto.

Assessment of benefits

3.28. The applicant referred to several benefits of the substance in their application.

Early control of broadleaf weeds in potato

3.29. The applicant explained that the use of herbicides, such as Soleto, especially in the early stages of crop emergence, were important to obtain acceptable yields.

3.30. The EPA considers that an efficacious product would be a significant benefit, but that the level of this is undetermined because ACVM assesses efficacy data.

Potential to replace the active substance linuron

3.31. The applicant explained that metobromuron has the potential to replace the active substance linuron, which is banned in Europe, as a pre-emergence herbicide. The EPA is unable to determine the level of this benefit, however notes the following:

3.32. The EPA notes that there are currently two active ingredients approved under the HSNO Act which, along with metobromuron, belong to the chemical family of Ureas, and are also used as pre-emergence herbicides in potatoes. Those are linuron (HSR003248) and methabenzthiazuron (HSR003524). The EPA notes that there are currently seven ACVM-approved substances containing linuron as the active ingredient and one ACVM-approved substance containing methabenzthiazuron as the active ingredient, with a use pattern similar to Soleto.

3.33. The EPA has identified ten HSNO-approved active ingredients for the pre-emergence control of weeds in potatoes.

Improvement of the resistance management strategy

3.34. The applicant explained that weed resistance is a well-known problem in agriculture and that it would be a benefit for the resistance management to add metobromuron, a new pre-emergence active substance belonging to the Urea chemical family.

3.35. The EPA considers that resistance management would be a significant benefit, but that the level of benefit is undetermined because ACVM assesses efficacy data. Nevertheless, the EPA notes that Soleto contains a new active ingredient which could provide an additional tool for farmers, therefore this is considered a significant benefit.

Low exposure to operators, workers and the environment

3.36. The applicant explained that the use pattern of Soleto (pre-emergence herbicide on bare soil) results in a minimum exposure for the operator, resident and bystander.

3.37. The EPA notes that the human health risk assessment results showed that predicted operator exposures to metobromuron during mixing, loading and application of Soleto were below the level of concern provided that full PPE is worn. The risks to re-entry workers were deemed below the level of concern without additional controls.

No residues on harvested products

3.38. The applicant explained that no residues are found in harvested commodities when metobromuron is used according the Good Agricultural Practices (GAP), resulting in a low risk potential to consumers.

3.39. The EPA notes that the presence of residues on harvested products is a matter assessed by ACVM, and therefore, the level of this benefit is undetermined.

Conclusions on the assessment of benefits

3.40. After considering the information that was presented, the Committee considered that there are potential benefits that will be derived for New Zealand by allowing the import or manufacture of Soleto.

4. Controls

4.1. The suite of controls proposed by the EPA include the prescribed controls triggered by the hazard classifications of Soleto, deletions and variations to the prescribed controls in accordance with section 77 of the Act, and additional controls proposed in accordance with section 77A. The Committee discussed and accepted these controls for Soleto.

Prescribed controls

4.2. The hazard classifications of Soleto determine a set of prescribed controls specified by the EPA Notices under section 77 of the Act. There are also requirements in the HSW (HS) Regulations. Note: the HSW (HS) Regulations requirements are not set for the substance under this approval but apply in their own right.

4.3. The prescribed controls set the baseline for how the substance must be managed and include specifications on how the substance is to be packaged, labelled, stored, disposed, transported, handled and used. The prescribed controls also set information requirements (eg Safety Data Sheets), signage and emergency management. These controls form the basis of the controls specified in the Appendix A.

4.4. Clause 17 of the Labelling Notice requires that certain toxic or corrosive components are identified on the product label. Section 3 of Schedule 1 of the Safety Data Sheet (SDS) Notice requires certain toxic or corrosive components are identified on the SDS. Section 8 of Schedule 1 of the SDS Notice requires occupational exposure limits to be identified on the SDS. Based on the information provided by the applicant, there is at least one component of Soleto that has a Workplace Exposure Value (WES) and this needs to be identified on the SDS.

Exposure limits

4.5. The Committee noted that the EPA has not set a Tolerable Exposure Limit (TEL) for Soleto, or any element or compound in the substance. This is because it is not considered that exposure is likely to result in an appreciable toxic effect based on the quantitative risk assessment. However, the Acceptable Daily Exposure (ADE) and Potential Daily Exposure (PDE) shown below are proposed by the EPA as health-based exposure guidance values that can be used to inform risk assessments as well as the setting of controls, such as Maximum Residue Levels (MRLs) under the Agricultural Compounds and Veterinary Medicines Act 1997.

4.6. The following values have been provided for metobromuron:

- ADE = 0.03 mg/kg bw/day
- PDE (food) = 0.021 mg/kg bw/day
- PDE (drinking water) = 0.006 mg/kg bw/day
- PDE (other) = 0.003 mg/kg bw/day

4.7. No Environmental Exposure Limit (EEL) values are proposed for metobromuron at this time. This is because it is not considered that, with controls in place, environmental exposure is likely to result in an appreciable ecotoxic effect based on the quantitative risk assessment.

Changes to prescribed controls

Maximum application rate

4.8. The Committee noted that the environmental assessment was based on the application rates proposed by the applicant, and therefore agreed with the EPA recommendation to propose a maximum application rate and number of applications. Therefore, the maximum application rate for Soleto is 4 L/ha (equivalent to 2 kg metobromuron/ha), with a maximum of one application per year.

Application method

4.9. The Committee noted that the environmental risk assessment was based on the application methods specified by the applicant. In particular, the restriction to apply Soleto via ground-based methods only, the restriction to a minimum medium droplet size and the restriction to favourable wind conditions are key factors in minimizing exposure to aquatic environments. The Committee agreed with the following EPA recommendations:

- Soleto can only be applied by ground-based methods.
- When Soleto is applied using ground-based methods, the nozzle must be set to a medium droplet quality spray, at a minimum, as defined by the American Society of Agricultural and Biological Engineers ASABE Standard (S572) or the British Crop Production Council guideline.
- Soleto 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

4.10. The Committee noted the EPA's recommendation to set a buffer zone to mitigate the risks from spray drift and runoff. The Committee agreed with the recommendation that Soleto must not be applied within 5 m of any waterbody.

Additional label statements

4.11. The Committee noted the EPA's recommendation to require an additional label statement to mitigate risks to non-target arthropods. The Committee agreed with the following recommended label statement:

- *"Ensure mechanical removal of weeds, remaining crop and seeds has taken place before application. The substance should only be used after planting and before crop emergence."*

4.12. The Committee noted the EPA's recommendation to require additional label statements to mitigate risks to non-target plants and limit off-target exposure. The Committee agreed with the following recommended label statements:

- *"**WARNING**, very toxic to some plant species. Certain plants may be damaged or killed from contact with this product. The substance should not be applied within 5 m of a downwind area containing any non-target plants."*
- *"Before application, users should check with the regional authority to establish if there are wetlands, indigenous vegetation habitat areas or reserves which may contain threatened plants adjacent to the application area, in which case it is recommended to increase the buffer zone to 50 m."*

4.13. The Committee noted the EPA's recommendation to require an additional label statement to mitigate general off-target exposure. The Committee agreed with the following recommended label statement:

- *"**DO NOT** apply when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site."*

Review of additional controls and variations

4.14. The Committee reviewed the additional controls and variations to the prescribed controls mentioned above and considered them necessary to achieve their purpose of effective risk management of the use of Soleto in New Zealand.

4.15. The full suite of controls, including variations, can be found in Appendix A of this document.

4.16. The applicant was given an opportunity to comment on the proposed controls as set out in the Science Memorandum. The applicant had no concerns with the controls, and the Committee has not made any changes to the controls recommended by the EPA.

5. Conclusion

5.1. Taking into account the assessment of the potential risks and benefits associated with Soleto, the Committee considered that, with all of the controls in place:

- The overall risks to human health and the environment arising from the hazardous properties and the use of Soleto are negligible, except for non-threatened species of soil mites and Collembola for which a low risk has been identified.
- Significant adverse impacts on the social or economic environment from the use of Soleto are not anticipated.
- If Soleto is applied in the proposed manner, it would likely be consistent with the principles of Te Tiriti o Waitangi (the Treaty of Waitangi). Significant impacts on Māori culture or traditional relationships with ancestral lands, water, wāhi tapu, valued flora and fauna or other taonga have not been identified.

- Significant benefits will be derived for New Zealand by allowing the use of Soleto.

5.2. Therefore, the Committee considered that benefits of the substance, based on the assessment of the information available, outweigh the risks of the substance.

6. Decision

6.1. Pursuant to section 29 of the Act, the Committee has considered this application for approval under section 28 of the Act. The Committee has considered the effects of this substance throughout the import and use phase of its life cycle, the controls that may be imposed on this substance and the likely effects of this substance being unavailable. The Committee has also taken into account the considerations set out in Part 2 of the Act.

6.2. The Committee was satisfied with the hazard classifications identified by the EPA in Table 1 and has applied these classifications to Soleto.

6.3. The Committee considered that, with controls in place, the risks to human health and to the environment will be negligible, and the benefits associated with the release of this substance will outweigh the adverse effects. Therefore, the application to import or manufacture Soleto for release is approved with controls in accordance with section 29 of the Act and clause 26 of the Hazardous Substances and New Organisms (Methodology) Order 1998.

Signed by: **Dr Louise Malone**	Date: **1 December 2020**
Chair, Decision Making Committee **Environmental Protection Authority**	

Appendix A: Controls applying to Soleto

EPA Controls

Control code	Regulation	Control description
LAB	EPA Labelling Notice 2017	Requirements for labelling of hazardous substances
PKG	EPA Packaging Notice 2017	Requirements for packaging of hazardous substances
SDS	EPA Safety Data Sheet Notice 2017	Requirements for safety data sheets for hazardous substances
DIS	EPA Disposal Notice 2017	Requirements for disposal of hazardous substances
HPC-1	EPA Hazardous Property Controls Notice 2017 Part 1	Hazardous Property Controls preliminary provisions
HPC-3	EPA Hazardous Property Controls Notice 2017 Part 3	Hazardous substances in a place other than a workplace
HPC-4A	EPA Hazardous Property Controls Notice 2017 Part 4A	Site and storage controls for class 9 substances
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B	Use of class 9 substances
HPC-4C	EPA Hazardous Property Controls Notice 2017 Part 4C	Qualifications required for application of class 9 pesticides

HSNO Additional Controls and Modifications to Controls

Code	HSNO Act	Control
Application rate	Section 77 variation to HPC notice clause 50	The maximum application rate of Soleto is 4 L/ha (equivalent to 2 kg metobromuron/ha), with a maximum frequency of one application per year.
Application method	Section 77A	Soleto can only be applied by ground-based methods. When applied using ground-based methods, the nozzle must be set to a medium droplet quality spray, at a minimum, as defined by the American Society of Agricultural and Biological Engineers ASABE Standard (S572) or the British Crop Production Council guideline. Soleto 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 77 variation to HPC notice clause 51	To mitigate risks from spray drift and runoff the substance should not be applied within 5 m of any waterbody.
Label	Section 77 variation to Labelling Notice	The substance label must include the following statements, or words to the same effect: • *"Ensure mechanical removal of weeds, remaining crop and seeds has taken place before application. The substance should only be used after planting and before crop emergence."* • *"**WARNING**, very toxic to some plant species. Certain plants may be damaged or killed from contact with this product. The substance should not be applied within 5 m of a downwind area containing any non-target plants."* • *"Before application users should check with the regional authority to establish if there are wetlands, indigenous vegetation habitat areas or reserves which may contain threatened plants adjacent to the application area, in which case it is recommended to increase the buffer zone to 50 m."* • *"**DO NOT** apply when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site."*

HSW HS 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.

Control code	Regulation	Control description
HSW2-1	Reg 2.1 - 2.4	Workplace labelling of hazardous substance containers
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
HSW13-2	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
HSW13-9	Reg 13.18	Duty of PCBU to ensure prescribed exposure standards for class 6 substances not exceeded
HSW13-14	Reg 13.30	Secondary containment requirements for class 6 and 8 pooling substances
HSW16-1	Part 16	Requirements for tank wagons and transportable containers
HSW17-1	Part 17	Requirements for stationary container systems

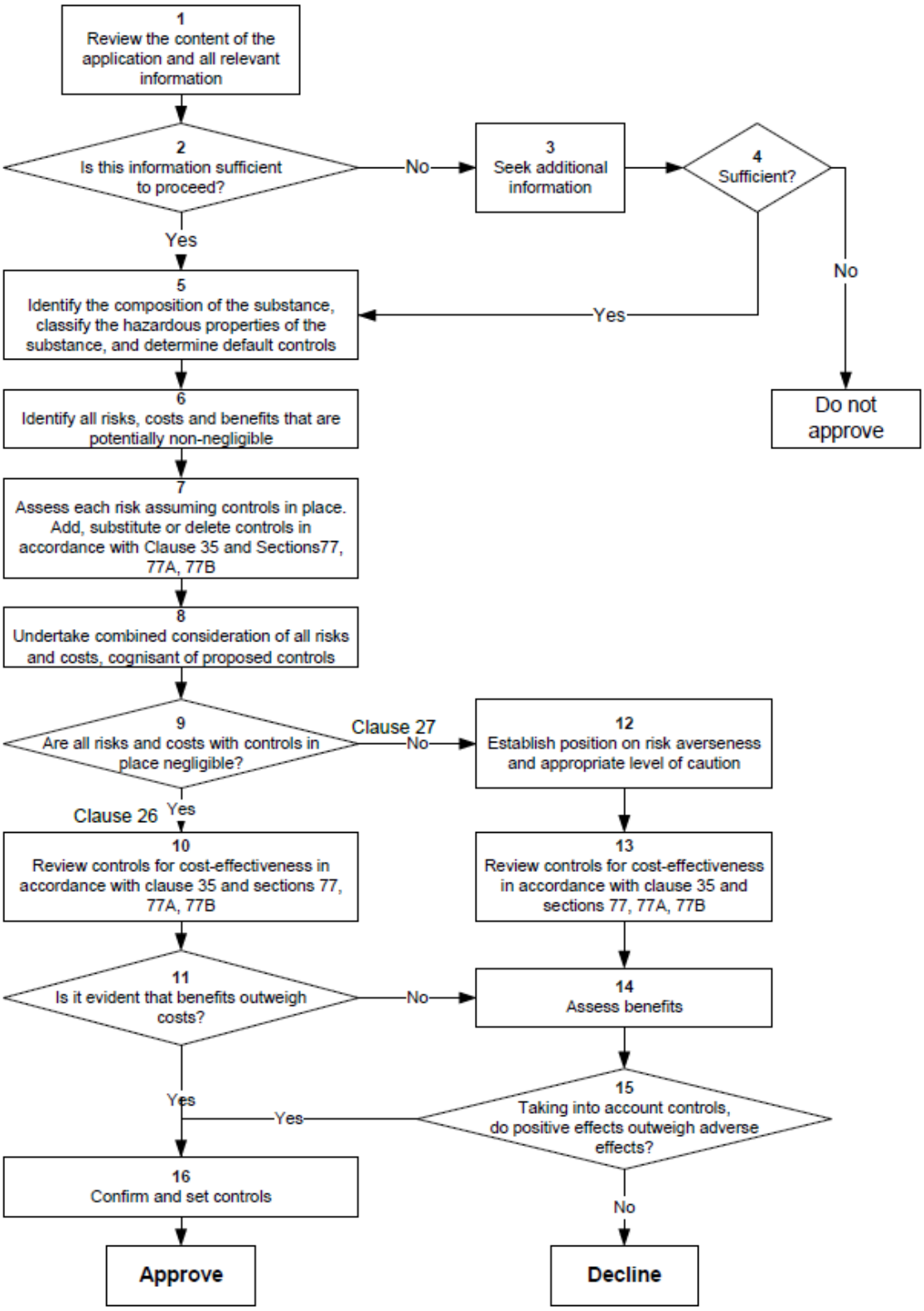
Appendix B: Decision Path

Context

This decision path describes the decision-making process for applications to import or manufacture a hazardous substance. These applications are made under section 28 of the HSNO Act and determined under section 29.

Decision path for applications to import or manufacture a hazardous substance, application made under section 28 of the Act and determined under section 29.

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



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.
Item 2:	**Is this information sufficient to proceed?** Review the information and determine whether or not there is sufficient information available to make a decision. The Methodology (clause 8) states that the information used by the HSNO decision maker in evaluating applications shall be that which is appropriate and relevant to the application. While the HSNO decision maker will consider all relevant information, its principal interest is in information which is significant to the proper consideration of the application; ie information which is "necessary and sufficient" for decision-making.
Item 3:	**(if 'no' from item 2) Seek additional information** If there is not sufficient information then additional information may need to be sought from the applicant, EPA staff or other parties/experts under section 58 of the Act (clause 23 of the Methodology).
Item 4	**Sufficient?** When additional information has been sought, has this been provided, and is there now sufficient information available to make a decision? If the HSNO decision maker is not satisfied that it has sufficient information for consideration, then the application must be declined under section 29(1)(c).
Item 5:	**(If 'yes' from item 2 or from item 4) Identify the composition of the substance, classify the hazardous properties, and determine default controls** Identify the composition of the substance, and establish the hazard classifications for the identified substance. Determine the default controls for the specified hazardous properties using the regulations "toolbox".
Item 6:	**Identify all risks, costs and benefits that are potentially non-negligible[2]** Costs and benefits are defined in the Methodology as the value of particular effects (clause 2). However, in most cases these „values" are not certain and have a likelihood attached to them. Thus costs and risks are generally linked and may be addressed together. If not, they will be addressed separately. Examples of costs that might not be obviously linked to risks are direct financial costs that cannot be considered as "sunk" costs (see footnote 1). Where such costs arise and they have a market economic effect they will be assessed in the same way as risks, but their likelihood of occurrence will be more certain (see also item 11). Identification is a two-step process that scopes the range of possible effects (risks, costs and benefits).

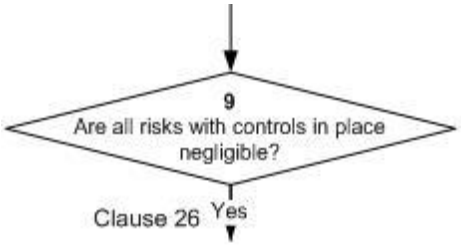
[2] Relevant effects are **marginal effects**, or the changes that will occur as a result of the substance being available. Financial costs associated with preparing and submitting an application are not marginal effects and are not effects of the substance(s) and are therefore not taken into account in weighing up adverse and positive effects. These latter types of costs are sometimes called "sunk" costs since they are incurred whether or not the application is successful.

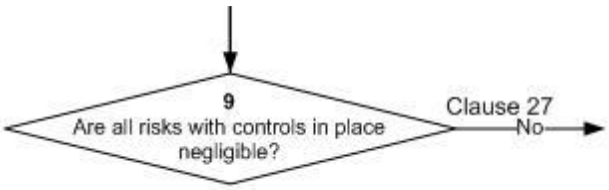
	Step 1:	Identify all possible risks and costs (adverse effects) and benefits (positive effects) associated with the approval of the substance(s), and based on the range of areas of impact described in clause 9 of the Methodology and sections 5 and 6 of the Act[3]. Consider the effects of the substance through its lifecycle (clause 11) and include the likely effects of the substance being unavailable (sections 29(1)(a)(iii) and 29(1)(b)(iii)). Relevant costs and benefits are those that relate to New Zealand and those that would arise as a consequence of approving the application (clause 14). Consider short term and long term effects. Identify situations where risks and costs occur in one area of impact or affect one sector and benefits accrue to another area or sector; that is, situations where risks and costs do not have corresponding benefits.
	Step 2:	Document those risks, costs and benefits that can be readily concluded to be negligible[4], and eliminate them from further consideration. Note that where there are costs that are not associated with risks some of them may be eliminated at this scoping stage on the basis that the financial cost represented is very small and there is no overall effect on the market economy.
Item 7:	**Assess each risk assuming controls in place. Add, substitute or delete controls in accordance with clause 35 and sections 77, 77A and 77B of the Act.** The assessment of potentially non-negligible risks and costs should be carried out in accordance with clauses 12, 13, 15, 22, 24, 25, and 29 to 32 of the Methodology. The assessment is carried out with the default controls in place. Assess each potentially non-negligible risk and cost estimating the magnitude of the effect if it should occur and the likelihood of its occurring. Where there are non-negligible financial costs that are not associated with risks then the probability of occurrence (likelihood) may be close to 1. Relevant information provided in submissions should be taken into account. The distribution of risks and costs should be considered, including geographical distribution and distribution over groups in the community, as well as distribution over time. This information should be retained with the assessed level of risk/cost. This assessment includes consideration of how cautious the HSNO decision maker will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the adverse effect as a means of identifying the range of uncertainty (clause 32). It is also important to bear in mind the materiality of the uncertainty and how significant the uncertainty is for the decision (clause 29(a)). Consider the HSNO decision maker's approach to risk (clause 33 of the Methodology) or how risk averse the HSNO decision maker should be in giving weight to the residual risk, where residual risk is the risk remaining after the imposition of controls. See EPA report 'Approach to Risk' for further guidance[5].	

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

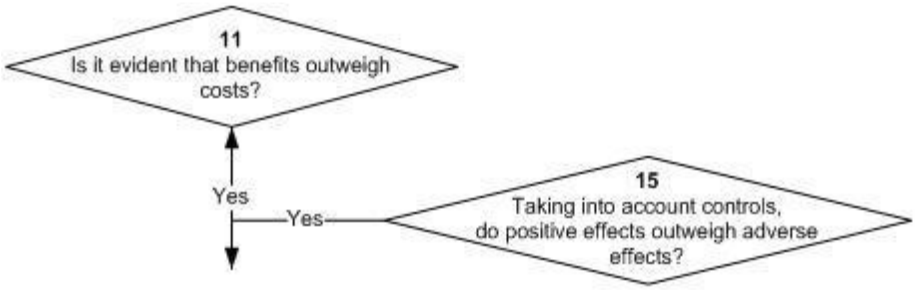
[4] Negligible effects are defined in the Annotated Methodology as "Risks which are of such little significance in terms of their likelihood and effect that they do not require active management and/or after the application of risk management can be justified by very small levels of benefits."

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

	Where it is clear that residual risks are non-negligible and where appropriate controls are available, add substitute or delete controls in accordance with sections 77 and 77A of the Act to reduce the residual risk to a tolerable level. If the substance has toxic or ecotoxic properties, consider setting exposure limits under section 77B. While clause 35 is relevant here, in terms of considering the costs and benefits of changing the controls, it has more prominence in items 10 and 13. If changes are made to the controls at this stage then the approach to uncertainty and the approach to risk must be revisited.
Item 8:	**Undertake combined consideration of all risks and costs, cognisant of proposed controls** Once the risks and costs have been assessed individually, if appropriate consider all risks and costs together as a “basket" of risks/costs. This may involve combining groups of risks and costs as indicated in clause 34(a) of the Methodology where this is feasible and appropriate, or using other techniques as indicated in clause 34(b). The purpose of this step is to consider the interactions between different effects and determine whether these may change the level of individual risks.
Item 9:	**Are all risks with controls in place negligible?** Looking at individual risks in the context of the “basket" of risks, consider whether all of the residual risks are negligible.
Item 10:	 **(from item 9 - if ‘yes’) Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B** Where all risks are negligible the decision must be made under clause 26 of the Methodology. Consider the practicality and cost-effectiveness of the proposed individual controls and exposure limits (clause 35). Where relevant and appropriate, add, substitute or delete controls whilst taking into account the view of the applicant, and the cost-effectiveness of the full package of controls.
Item 11:	**Is it evident that benefits outweigh costs?** Risks have already been determined to be negligible (item 9). In the unusual circumstance where there are non-negligible costs that are not associated with risks they have been assessed in item 7. Costs are made up of two components: internal costs or those that accrue to the applicant, and external costs or those that accrue to the wider community. Consider whether there are any non-negligible external costs that are not associated with risks. If there are no external non-negligible costs then external benefits outweigh external costs. The fact that the application has been submitted is deemed to demonstrate existence of

	internal or private net benefit, and therefore total benefits outweigh total costs[6]. As indicated above, where risks are deemed to be negligible, and the only identifiable costs resulting from approving an application are shown to accrue to the applicant, then a cost-benefit analysis will not be required. The act of an application being lodged will be deemed by the 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 14).
Item 12:	 **(if 'no' from item 9) Establish position on risk averseness and appropriate level of caution** Although "risk averseness" (approach to risk, clause 33) is considered as a part of the assessment of individual risks, it is good practice to consolidate the view on this if several risks are non-negligible. This consolidation also applies to the consideration of the approach to uncertainty (section 7).
Item 13:	**Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B** This constitutes a decision made under clause 27 of the Methodology (taken in sequence from items 9 and 12). Consider whether any of the non-negligible risks can be reduced by varying the controls in accordance with sections 77 and 77A of the Act, or whether there are available more cost-effective controls that achieve the same level of effectiveness (section 77A(4)(b) and clause 35(a)). Where relevant and appropriate, add, substitute or delete controls whilst taking into account the views of the applicant (clause 35(b)), and making sure that the total benefits that result from doing so continue to outweigh the total risks and costs that result. As for item 7, if the substance has toxic or ecotoxic properties, consider exposure limits under section 77B.
Item 14:	**(if 'no' from item 11 or in sequence from item 13) Assess benefits** Assess benefits or positive effects in terms of clause 13 of the Methodology. Since benefits are not certain, they are assessed in the same way as risks. Thus the assessment involves estimating the magnitude of the effect if it should occur and the likelihood of it occurring. This assessment also includes consideration of the 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.

[6] Technical Guide "Decision making" section 4.9.3. Where risks are negligible and the costs accrue only to the applicant, no explicit cost benefit analysis is required. In effect, the HSNO decision maker takes the act of making an application as evidence that the benefits outweigh the costs. See also Protocol Series 1 "General requirements for the Identification and Assessment of Risks, Costs, and Benefits".

	An understanding of the distributional implications of a proposal is an important part of any consideration of costs and benefits, and the distribution of benefits should be considered in the same way as for the distribution of risks and costs. The HSNO decision maker will in particular look to identify those situations where the beneficiaries of an application are different from those who bear the costs[7]. This is important not only for reasons related to fairness but also in forming a view of just how robust any claim of an overall net benefit might be. It is much more difficult to sustain a claim of an overall net benefit if those who enjoy the benefits are different to those who will bear the costs. Thus where benefits accrue to one area or sector and risks and costs are borne by another area or sector then the HSNO decision maker may choose to be more risk averse and to place a higher weight on the risks and costs. As for risks and costs, the assessment is carried out with the default controls in place.
Item 15:	**Taking into account controls, do positive effects outweigh adverse effects?** In weighing up positive and adverse effects, consider clause 34 of the Methodology. Where possible combine groups of risks, costs and benefits or use other techniques such as dominant risks and ranking of risks. The weighing up process takes into account controls proposed in items 5, 7, 10 and/or 13. Where this item is taken in sequence from items 12, 13 and 14 (i.e. risks are not negligible) it constitutes a decision made under clause 27 of the Methodology. Where this item is taken in sequence from items 9, 10, 11 and 14 (i.e. risks are negligible, and there are external non-negligible costs) it constitutes a decision made under clause 26 of the Methodology.
Item 16:	 **(if 'yes' from items 11 or 15) Confirm and set controls** Controls have been considered at the earlier stages of the process (items 5, 7, 10 and/or 13). The final step in the decision-making process brings together all the proposed controls, and reviews for overlaps, gaps and inconsistencies. Once these have been resolved the controls are confirmed.

[7] This principle derives from Protocol Series 1, and is restated in the Technical Guide "Decision making".