Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

12 APRIL 2022

Summary

Substance	XIVANA
Application code	APP204042
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	Bayer New Zealand Limited
Purpose of the application	To import or manufacture XIVANA for release
Considered by	A Decision-Making Committee of the Environmental Protection Authority ("the Committee"): Dr Kerry Laing (Chair) Dr Philip Lester Mr Greg Percival
Decision	**Approved with controls**
Approval code	**HSR101531**
Hazard classifications	Skin sensitisation Category 1B, hazardous to the aquatic environment chronic Category 3

Application dates	
Date application formally received	4 September 2020
Submission period	17 November 2021 – 26 January 2022
Consideration date	10 March 2022 – 12 April 2022
Date decision signed	12 April 2022

1. Application context

Background

1.1. The applicant, Bayer New Zealand Limited, submitted an application on 12 May 2020 to import or manufacture XIVANA for release in New Zealand. It was given application number APP204042 and was formally received as a notified Category C application.

1.2. XIVANA is intended to be used as a fungicide for the control of downy mildew in onions and late blight in tomatoes and potatoes.

1.3. XIVANA is in the form of a suspension concentrate containing 20 g/L fluoxapiprolin as the active ingredient.

1.4. The active ingredient, fluoxapiprolin, has not previously been approved in New Zealand and no overseas jurisdictions have approved this active ingredient to date. An application for the approval of fluoxapiprolin is currently under evaluation in Europe.

1.5. The applicant has proposed an application rate of 1 L of XIVANA per hectare (equivalent to 20 g fluoxapiprolin per hectare), with a maximum frequency of three applications per season, and a minimum time between applications of seven days.

Process, consultation and notification

Application receipt

1.6. The application was formally received on 4 September 2020 under section 28 of the Act.

Notification to government departments

1.7. The following government departments were notified of the submission period on 17 November 2021: the Ministry for the Environment, the Ministry of Health, the Agricultural Compounds and Veterinary Medicines (ACVM) group of the Ministry for Primary Industries (MPI) and the Department of Conservation (DOC). No comments were received.

1.8. As 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 also sought from WorkSafe New Zealand (“WorkSafe”) on whether the HSW requirements are adequate to manage the risks associated with the use of this substance in the workplace.

1.9. WorkSafe noted that XIVANA contains a non-active ingredient component that introduces an additional hazard classification and that component may not be required for efficacy of the substance. Under sections 39 to 42 of the HSW Act, manufacturers, importers and suppliers have a duty to ensure that substances manufactured, imported or supplied are without risk so far as is reasonably practicable. WorkSafe advised that duties under section 39 to 42 may not have been met for this substance as a result. The full advice is available in a separate report provided by WorkSafe on the EPA website.

Public notification

1.10. This application was publicly notified under section 53(2) of the Act, and public submissions were sought from 17 November 2021 to 26 January 2022. The EPA received five submissions on the application.

Timeframe waiver

1.11. The timeframe for the opening of the public consultation was waived under section 59 of the Act to allow for the preparation of the draft Science Memorandum, which contains the EPA risk assessment, in order to allow any potential submitter to have this document available to assist in making an informed submission.

Submissions received

1.12. Five submissions were received for XIVANA. Two submissions, from Onions New Zealand and Process Vegetables NZ supported the application, while three submissions, from Te Rūnanga o Ngāi Tahu (Ngāi Tahu), Fonterra Cooperative Group Ltd, and one other submitter (who elected to withhold their personal details) opposed the application.

Hearing

1.13. A public hearing was held on 10 March 2022 by video conference. Present via video were the Decision-Making Committee ("the Committee"), the applicant and representatives, EPA staff, and representatives from Ngāi Tahu. The hearing closed on 10 March 2022.

Legislative criteria for the application

1.14. 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 classifications and properties of the active ingredient, fluoxapiprolin, in XIVANA were determined by the EPA based on toxicological and ecotoxicological studies conducted using the technical grade active ingredient. The EPA also identified the classifications of XIVANA, which were based on formulation data, the composition of the substance, and the properties of its components.

2.3. Based on all available information, the EPA assessed the potential risks the substance may pose to human health, the environment, the relationship of Māori to the environment, society, community, and to the market economy.

2.4. The EPA conducted quantitative human health and environmental risk assessments to determine if the exposure experienced by people and organisms during the use of the substance was likely to result in adverse effects.

2.5. The EPA also considered whether there were benefits associated with the use of XIVANA.

2.6. The EPA identified a suite of prescribed controls based on the hazard classifications of XIVANA, and considered variations to these controls, as well as additional controls, in accordance with sections 77 and 77A of the Act.

2.7. The Staff Report (published on 18 February 2022) concluded that there was sufficient information available to assess the application to import or manufacture XIVANA 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 XIVANA would be negligible.

2.8. The Staff Report concluded, based on the assessment of the information available and with the proposed controls in place that benefits of the substance outweighed the risks of the substance. The Staff Report therefore recommended to the Committee that the application for the importation and manufacture of XIVANA be approved.

3. The hearing

3.1. On 10 March 2022, a public hearing for XIVANA was held virtually by video conference. Richard Mohan, Sue Cross, Sylvain Tafforeau, Andreas Mehl, Maura Karina and Chris Miln presented on behalf of the applicant (Bayer New Zealand Limited). Régis Lapage, Michael Berardozzi, and Julian Jackson presented on behalf of the EPA. A presentation was also made by Ngāi Tahu, represented by Dwayne Bennett and Stephanie Dijkstra.

3.2. The presentation from the applicant included information on the new active ingredient to New Zealand and stated that registrations were pending in other overseas jurisdictions. The applicant also presented the following information:

- XIVANA had high efficacy against late blight in potatoes and tomatoes and downy mildew in onions, with limited fungicides on the market to combat these
- XIVANA was one of the least hazardous fungicides with lower application rates than alternative fungicides on the market
- Māori were unlikely to be adversely affected from the use of XIVANA
- The new mode of action of the active ingredient (ie inhibiting of the oxysterol binding protein involved in the movement lipids between membranes).
- The development of resistance to XIVANA was considered medium to high, therefore, tank-mixing XIVANA with non-cross resistant compounds with different modes of action was recommended as a resistance management strategy.
- Addressed concerns regarding fluoxapiprolin-resistant mutant strains in laboratory studies, noting mutant development was a natural occurrence for many species and that laboratory studies would not necessarily be repeated in the field.

3.3. The presentation from the EPA briefly described XIVANA, including its use pattern, and the submissions that were received. The EPA also highlighted that fluoxapiprolin was a new active ingredient to New Zealand and had not been approved in any other major overseas jurisdictions. The EPA also presented the following information:

- The characteristics of the active ingredient, including its mode of action, hazard classification and bioaccumulative and persistence properties
- The hazard classifications of the formulated product XIVANA and how these were derived
- The approach taken with the human health risk assessment and also noted WorkSafe's remarks on sections 39 to 42 of the Health and Safety at Work (HSW) Act may not have been met due to introduction of an additional hazard classification from components, not the active ingredient

- The approach taken with the environmental risk assessment, concluding that risks to the environment were below the level of concern and that no additional risk mitigation measures were required
- Māori Impact Assessment concluded that XIVANA was not likely to adversely affect the economic, social and cultural well-being of Māori, nor was it likely to affect the relationship of Māori with their environment, taonga, and tikanga. The EPA found no issues in relation to the principles of the Treaty of Waitangi or potential effects on taha hauroa (human health and well-being) of Māori communities with the proposed controls
- The benefits of XIVANA claimed by the applicant and some submitters
- The proposed controls
- The recommendation to approve XIVANA with controls

3.4. The presentation from Ngāi Tahu described the reasons for submitting on the application for XIVANA. Ngāi Tahu highlighted the diversity of their takiwā (tribal territory) that covers up to 70% of the South Island (totalling 40% of New Zealand). Ngai Tahu also presented on the following information, which had been included in their submission:

- Concern over the aquatic toxicity, potential runoff, lack of buffer zone, as well as XIVANA's use at any time of the year, potentially impacting spawning species
- Concern over the contact [skin] sensitisation hazard
- Concern over potential for oomycete mutants, development of fungicide resistance and gave examples of oomycetes species potentially affecting human health, as well as being responsible for Kauri dieback
- Concern over New Zealand being the first in the world to potentially approve the active ingredient.

3.5. The Committee, applicant, EPA and Ngāi Tahu had the opportunity to ask questions to each of the presentations.

3.6. The applicant also had a right of reply, which reiterated information on being the first in the world to approve XIVANA, the lack of buffer zones required, the resistant management strategies, the lack of concern over resistance in Kauri dieback based on recommended use, the low application rates and good safety profile of the substance.

3.7. The Committee considered whether XIVANA would be another "tool" in the toolbox for growers by offering a different mode of action.

3.8. The Committee considered being the first in the world to approve the active ingredient.

3.9. The Committee considered and acknowledged concerns over resistance development, and also considered the recommendations for XIVANA to be tank-mixed with other fungicides with a different mode of action.

3.10. The Committee considered whether there would be an expectation of XIVANA to replace other older fungicides off the market.

3.11. The Committee considered whether the substitution of components in the formulation [ie the component triggering skin sensitisation] was viable.

3.12. The Committee considered the concerns over runoff as mentioned by Ngāi Tahu in their presentation.

4. Consideration

4.1. The application was considered by the Committee on 10 March 2022, following the decision pathway (available in Appendix A).

4.2. The following information was available to the Committee for consideration of this application:

- application form
- confidential material submitted by the applicant with the application form, including toxicological, ecotoxicological, and environmental fate studies on fluoxapiprolin and XIVANA
- the submissions
- the Māori Impact Assessment
- information received from WorkSafe
- the EPA Staff Report and Science Memorandum
- hearing presentations made by the applicant, EPA staff and Ngāi Tahu.

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

Hazard classifications

4.4. The Committee adopted the hazard classifications for XIVANA 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 classification differed from those proposed by the applicant (see Table 1).

Table 1: Hazard classifications of XIVANA

Hazard class	Applicant classification[1]	EPA classification
Respiratory or skin sensitisation	6.5B (HSNO classification)	skin sensitisation Category 1B[2]
Specific target organ toxicity – single exposure	**6.9B** **(HSNO classification)**	**No**
Specific target organ toxicity – repeated exposure	**6.9B** **(HSNO classification)**	**No**
Hazardous to the aquatic environment	**9.1D** **(HSNO classification)**	**hazardous to the aquatic environment chronic Category 3**

[1] The applicant proposed HSNO classifications. The EPA adopted the GHS classification after the application was submitted.

[2] Sub-categories 1A and 1B form part of Category 1 and are used when data are sufficient to allow the allocation of sensitisers into these sub-categories. In the case of APP204042, information provided by the applicant allowed the allocation of XIVANA in the sub-category 1B, which corresponds to substances showing a low to moderate frequency of occurrence in humans and/or a low to moderate potency in animals can be presumed to have the potential to produce skin sensitisation in humans (see Guide to classifying hazardous substances in New Zealand for more details).

Risk assessment

4.5. The Committee took into account the EPA risk assessment for XIVANA as detailed in the Science Memorandum. The risk assessment considered the import and use phases of the life cycle of the substance, including import, packaging, transport, storage, use and disposal. The key points are summarised below.

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

4.6. The applicant intends to import XIVANA into New Zealand, packaged and ready for sale, however relabelling will be carried out in New Zealand. The Committee considered that compliance with the proposed controls and other legislative requirements would ensure that the level of risk to human health and the environment from the importation, transportation, storage and disposal of XIVANA would be negligible.

Risks during use

Assessment of risks to human health

4.7. The Committee noted that the quantitative risk assessment conducted by the EPA determined that risks to operators during mixing, loading and applying XIVANA by ground-based or aerial application methods were below the level of concern even without the use of personal protective equipment (PPE). Although the quantitative risk assessment indicated that PPE was not required to ensure that exposures were below the level of concern, the requirements under the Health and Safety at Work (Hazardous Substances) Regulations, and in particular Regulations 13.7 and 13.8, state that PPE is to be used to minimise risks to the health and safety of workers.

4.8. The Committee noted that the EPA risk assessment determined that risks were below the level of concern for workers re-entering and working in affected areas and that no restricted entry intervals were necessary for XIVANA.

4.9. The Committee noted that the estimated risks to bystanders from spray drift were below the level of concern and that no buffer zones were proposed.

Assessment of risks to the environment

4.10. The Committee noted that the EPA conducted a quantitative risk assessment to determine the risks XIVANA posed to target and non-target organisms in the environment. The following areas were considered to be below the level of concern:

- Aquatic organisms
- Groundwater
- Sediment-dwelling organisms
- Non-target plants
- Birds (the risks from secondary poisoning was considered low)

- Pollinators and non-target arthropods.

4.11. The full environmental risk assessment can be found in Appendix H of the Science Memorandum for XIVANA.

Māori impacts

4.12. The Committee considered the concerns that Ngāi Tahu highlighted in their submission and hearing presentation.

4.13. The Committee noted that it had integrated these concerns into the assessment of risks and benefits when making its decision on this application.

4.14. The Committee noted that Kaupapa Kura Taiao (the EPA's Māori Policy and Operations team) undertook a Māori impact assessment (MIA) to consider potential impacts of the application on the economic, social, and cultural well-being of Māori, and the relationship of Māori with the environment, pursuant to sections 5(b), 6(d) and 8 of the HSNO Act. The MIA included tangible and intangible taonga, such as culturally significant species, resources, and places, and the customary values, practices and uses associated with these taonga.

4.15. Based on the MIA 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 XIVANA 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

4.16 The Committee considered that the overall level of risk to society, communities and the market economy from the approval of XIVANA would be negligible when proposed controls were followed.

New Zealand's international obligations

4.17 The Committee noted that no international obligations will be impacted by the approval of XIVANA.

Assessment of benefits

4.18 The applicant referred to several benefits of the substance in their application:

- New mode of action and resistance management
- Good rainfastness
- High level of efficacy
- Residues on harvested crops expected to be below Limit of Quantification (LoQ)
- Lower hazard profile and application rate than currently used alternative substances

4.19 The Committee noted that the benefits of good rainfastness, high efficacy and low residues could not be determined as they fell outside of the scope of the Committee's consideration.

Conclusion on the assessment of risks and benefits

4.20 The overall risk and benefit assessment:

- Considered the risks posed by XIVANA
- Determined whether the risks are outweighed by the benefits
- Determined whether any variations or additions to the prescribed controls were required to manage the risks of this substance, and identified controls that may not have been applicable or necessary that could, therefore, be deleted.

4.21 After considering the information that was presented, the Committee considered that there were potential benefits that would be derived for New Zealand by allowing the import or manufacture of XIVANA.

5. Controls

5.1. The hazard classifications of XIVANA 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.

5.2. 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 of the Approval document for XIVANA.

Exposure limits

5.3. The Committee noted that the EPA did not set a Tolerable Exposure Limit (TEL) for XIVANA, or any element or compound in the substance. This is because it was not considered that exposure was 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 were proposed by the EPA as health-based exposure guidance values that could 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.

5.4. The following values have been provided for fluoxapiprolin:

- ADE = 0.55 mg/kg bw/day
- PDE(food) = 0.385 mg/kg bw/day
- PDE(drinking water) = 0.11 mg/kg bw/day
- PDE(other) = 0.05 mg/kg bw/day

5.5. The Committee noted that no Environmental Exposure Limit (EEL) values were proposed for fluoxapiprolin to date. This was because it was not considered that, with controls in place, environmental exposure was likely to result in an appreciable ecotoxic effect based on the quantitative risk assessment.

5.6. There are Workplace Exposure Standard (WES) values currently set for components of XIVANA but, as they are not Prescribed Exposure Standard (PES) values, they are guidance values used for the management of health risk. No PES has been set for any component of XIVANA.

Variation of prescribed control

5.7. The following variation to clause 50 of the Hazardous Property Controls (HPC) Notice (Part 4B) is proposed under section 77A of the Act to manage the risks of use of XIVANA.

Maximum application rate

5.8. The Committee noted that the environmental risk assessment was based on the application rates proposed by the applicant. Therefore, it was considered necessary to propose a maximum application rate, number of applications and frequency.

5.9. The maximum application rate for XIVANA is 1 L/ha (equivalent to 20 g fluoxapiprolin/ha), with a maximum frequency of three applications per year, and a minimum interval of seven days between applications.

Review of variation to prescribed control

5.10. The Committee reviewed the variation to the prescribed control for the maximum application rate and considered it necessary to achieve the purpose of effective risk management of the use of XIVANA in New Zealand.

5.11. The full suite of controls, including any variations, can be found in the Appendix A of the Approval document for XIVANA.

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

6. Conclusion

6.1. After taking into account the assessment of the potential risks and benefits associated with XIVANA, 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 XIVANA are negligible;
- Significant adverse effects on the social or economic environment or international obligations from the use of XIVANA are not anticipated;
- If XIVANA is applied in the proposed manner, it would likely be consistent with the principles of Te Tiriti o Waitangi (the Treaty of Waitangi);
- Significant benefits will be derived for New Zealand by allowing the use of XIVANA.

7. Decision

7.1. 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 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.

7.2. The Committee has considered that, with controls in place, the risks to human health and to the environment are negligible, and the benefits associated with the release of this substance will outweigh the adverse effects. Therefore, the application to import or manufacture XIVANA 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 Kerry Laing	Date: 12 April 2022
Chair, Decision-Making Committee, Environmental Protection Authority	

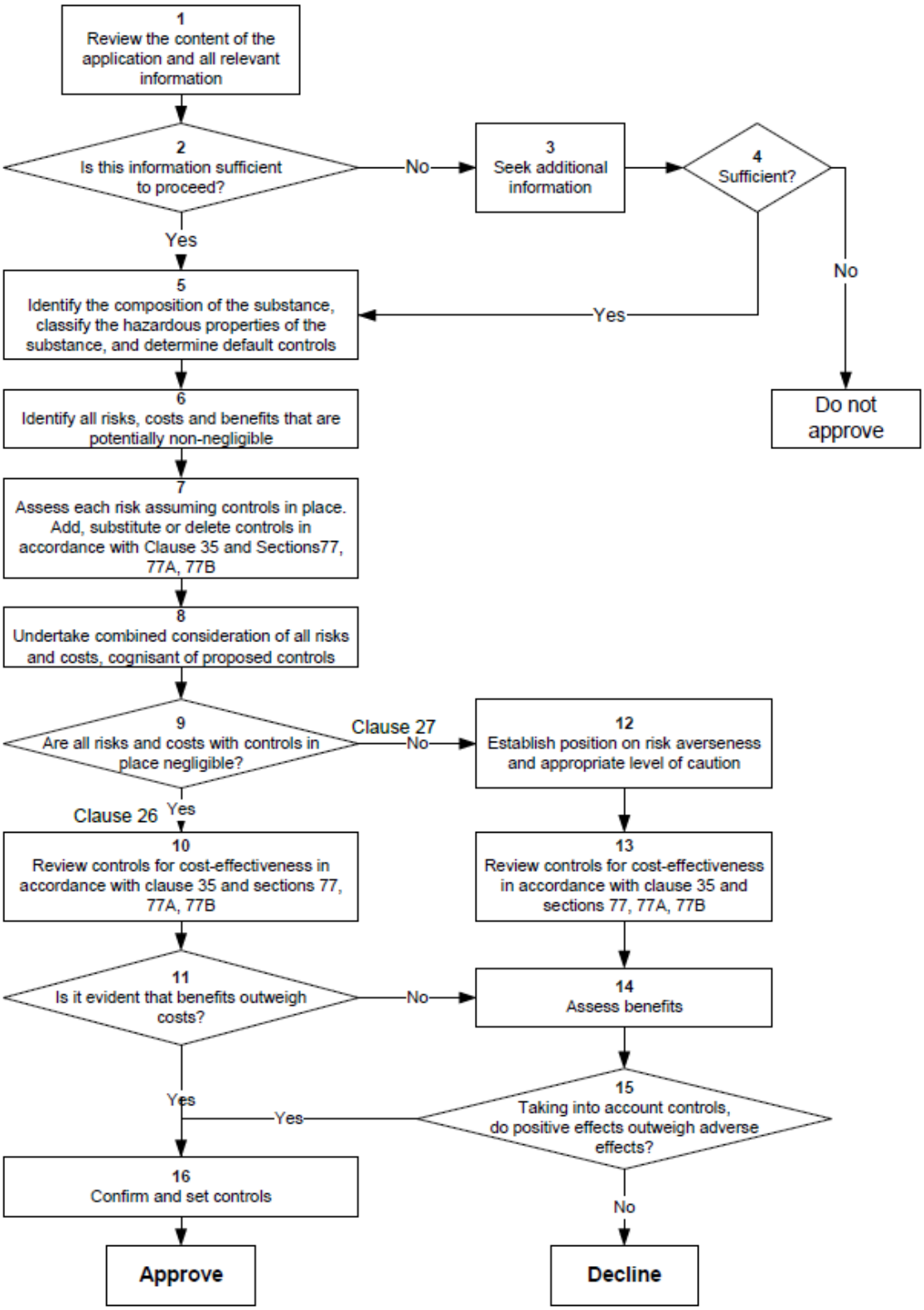
Appendix A: Decision path

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**[3] 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 2). 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).

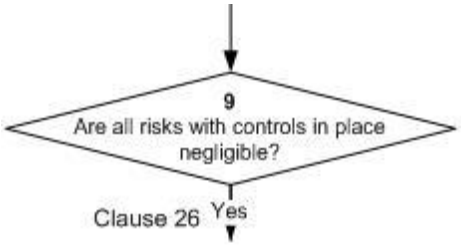
[3] Relevant effects are **marginal effects**, or the changes that will occur as a result of the substance being available. Financial costs associated with preparing and submitting an application are not marginal effects and are not effects of the substance(s) and are therefore not taken into account 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.

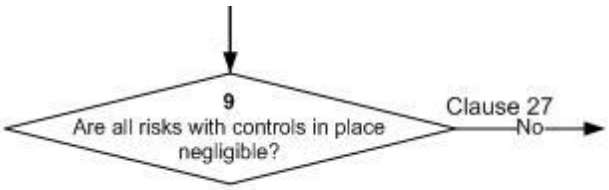
	Step 1:	Identify all possible risks and costs (adverse effects) and benefits (positive effects) associated with the approval of the substance(s), and based on the range of areas of impact described in clause 9 of the Methodology and sections 5 and 6 of the Act[4]. Consider the effects of the substance 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[5], 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[6].

[4] 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.

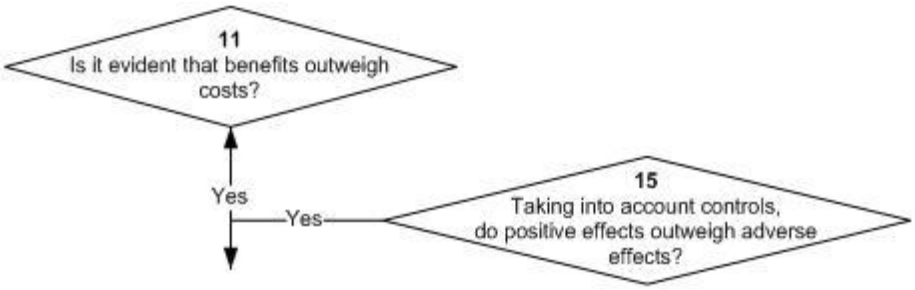
[5] Negligible effects are defined in the Annotated Methodology as "Risks which are of such little significance in terms of their likelihood and effect that they do not require active management and/or after the application of risk management can be justified by very small levels of benefits".

[6] 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[7]. 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.

[7] 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[8]. 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 (ie 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 (ie 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.

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