Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

8 SEPTEMBER 2020

Summary

Substance	AMICUS
Application code	APP203794
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	Nufarm Limited
Purpose of the application	To import or manufacture AMICUS for release
Information requests and time waivers	The timeframe for consideration of this application was waived under section 59 of the Act
Submissions received	Six submissions were received: Lynne Clapham Crystal Epps Gilda Hessel Esteban Ibanez, Leaderbrand South Island Limited Gerry Te Kapa Coates, Ngāi Tahu HSNO Kōmiti Vegetable Research and Innovation Board
Considered by	A Decision-Making Committee of the Environmental Protection Authority (“the Committee”): Dr Ngaire Phillips (Chair) Dr Kerry Laing Dr Nick Roskruge
Decision	**Approved with controls**
Approval code	**HSR101440**
Hazard classifications	6.7B, 9.1A

Application dates	
Date application formally received	23 May 2019
Submission period	7 June 2019 – 19 July 2019
Hearing date	31 July 2020
Consideration date	31 July 2020 – 7 September 2020
Date decision signed	7 September 2020

1. Application context

Background

1.1. The applicant, Nufarm Limited, submitted an application on 15 January 2019 to import or manufacture[1] for release AMICUS into New Zealand. It was given the application number APP203794 and was formally received on 23 May 2019 as a notified Category C application.

1.2. AMICUS is the substance name for wettable granules containing 500 g/kg of amisulbrom as the active ingredient. Amisulbrom is a new active ingredient to New Zealand and is approved in Europe, Australia and Japan for use as a fungicide. It is not approved in Canada and is under evaluation in the USA.

1.3. AMICUS is intended to be used as a fungicide for the control of clubroot in transplanted brassica crops and powdery scab in potatoes (by non-dispersive drenching and in-furrow spray methods, respectively).

1.4. In the application form, the non-dispersive drenching method was described as consisting of vegetable brassica transplants being soaked in “bins” prior to planting in the field. The seedling drench would then be applied at low pressure over the transplants, targeting the water that they soaked in rather than the plants themselves. During the hearing, the applicant explained that the drenching process would generally involve the substance being applied over the tops of the seedlings sitting in trays in a nursery. The application of the substance would only be enough to wet the plugs of the seedlings.

1.5. The in-furrow spray method for potatoes consists of the substance being applied at planting time directly into the open furrow along with the potato. The delivery nozzles are essentially at ground level, and the furrow is closed over after spraying.

1.6. The maximum application rate for vegetable brassicas is 0.7 kg amisulbrom/ha, with a maximum of one application per year. The maximum application rate for potatoes is 2.5 kg amisulbrom/ha, with a maximum of one application per year.

Process, consultation and notification

1.7. The application was formally received on 23 May 2019 under section 28 of the Act.

Notification to government departments

1.8. The following government departments were notified of the application on 23 May 2019: the Ministry for the Environment, the Ministry of Health, the Agricultural Compounds and Veterinary Medicines (ACVM) group of the Ministry for Primary Industries and the Department of Conservation. No comments were received.

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

1.9. 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. WorkSafe was notified of the application on 23 May 2019 and was provided with the appropriate documents to allow them to provide this advice.

1.10. In their response, WorkSafe identified that the Person Conducting a Business or Undertaking (PCBU) may not have gone so far as reasonably practicable to ensure that the substance manufactured, imported or supplied was without risk. For AMICUS, WorkSafe stated that the duties under sections 39 to 42 of the HSW Act may not have been met. However, WorkSafe considered that compliance with the HSW (HS) Regulations and Health and Safety at Work (General Risk and Workplace Management) Regulations would be adequate to reduce the risks associated with the use of this substance in the workplace. The full advice is available in a separate report provided by WorkSafe.

Public notification

1.11. This application was publicly notified under section 53 of the Act as it was considered likely that there would be significant public interest in the application. This is because AMICUS contains a new active ingredient that has not previously been assessed under the Act.

1.12. The application was open for submissions from 7 June 2019 to 19 July 2019.

Timeframe waiver

1.13. The statutory timeframe for the holding of the hearing of this application was waived on 5 August 2019 under section 59 of the Act to allow for the assessment of a large volume of information.

Submissions

1.14. Six submissions were received on the application.

1.15. Three submissions supported the application. These were from Leaderbrand South Island Limited, the Vegetable Research and Innovation Board and one member of the public.

1.16. Three opposed the application. These were from Ngāi Tahu HSNO Kōmiti and two members of the public.

1.17. Three submitters initially indicated that they wished to be heard at the public hearing, however, prior to the hearing, two submitters withdrew from the hearing proceedings and another submitter elected to be heard at the hearing.

Hearing

1.18. The hearing was held on 31 July 2020 by video conference. Present via video were the Decision-Making Committee ("the Committee"), the applicant and representatives, the EPA, the Ngāi Tahu

HSNO Kōmiti and the Vegetable Research and Innovation Board. The hearing closed on 31 July 2020.

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;
- submissions;
- information received from WorkSafe;
- hearing presentations made by the applicant, the EPA and submitters;
- the cultural assessment;
- EPA Staff Report and Science Memorandum.

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

Legislative criteria for the application

1.21. 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, amisulbrom, in AMICUS based on toxicological and ecotoxicological studies conducted using the technical grade active ingredient. The EPA then identified the classifications of the substance AMICUS, 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 that 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 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 AMICUS and considered variations to these controls, including maximum applications rates, number of applications, frequency and specific application methods, and the addition of controls, including wind speed and maximum impurity allowances, in accordance with sections 77 and 77A of the Act.

2.6. The EPA Staff Report (dated June 2020) concluded that there was sufficient information available to assess the application to import or manufacture AMICUS for release, and that with the proposed controls in place, the risks to human health and the environment from the importation, manufacture and use of AMICUS are negligible. The Staff Report also concluded that the use of AMICUS would provide some benefits to users, and that with the proposed controls in place, the benefits would outweigh the risks of the substance.

3. The hearing

3.1. The hearing for AMICUS was held on 31 July 2020 by video conference. Emma Waller, Duncan Ibbotson and Alan Cliffe presented on behalf of the applicant (Nufarm Limited). Régis Lapage, Michael Berardozzi and Julian Jackson presented on behalf of the EPA. Presentations were also given on behalf of Ngāi Tahu HSNO Kōmiti by Stephanie Dijkstra, and the Vegetable Research and Innovation Board by Dr Sally Anderson.

Applicant's presentation

3.2. The applicant introduced the company, Nufarm Limited, then gave an overview of AMICUS, describing the intention to use amisulbrom, the active ingredient of AMICUS, as a seedling drench for brassicas and an in-furrow spray for potatoes. The applicant stated that Amisulbrom and AMICUS were

developed in Japan, with Nufarm Australia and Nufarm New Zealand being the regional distributers of amisulbrom in this region. The applicant also noted that the product trade name had changed from AMICUS to AmiShield.

3.3. The applicant noted that amisulbrom was a new active ingredient to New Zealand and commented on the other jurisdictions where the active ingredient was registered or where the same or similar formulated product was under evaluation.

3.4. The applicant described the use rates for AMICUS on vegetable brassica and potato crops and stated that it was likely that the application rate would be lower for potatoes than what was outlined in the Good Agricultural Practice (GAP) table submitted with their application form.

3.5. The applicant explained that amisulbrom was assigned to Group 21 of the Quinone inside Inhibitor (Qil) Mode of Action Group by the Fungicide Resistance Action Committee (FRAC). While resistance was not known to amisulbrom, the development of resistance was likely to be medium to high, therefore, a resistance management strategy was to be implemented and the applicant stated that they would be placing a relevant statement on their label to highlight this.

3.6. The applicant then noted that the submitters for this application highlighted the lack of information provided in the application form and further noted that it understood that the EPA was changing their processes to allow the science memorandum to be released prior to public submission.

3.7. The applicant gave an overview of the classifications and the proposed controls for AMICUS produced by the EPA. The applicant noted that, while the 6.7B classification given by the EPA was consistent with European Chemicals Agency (ECHA) and the US EPA, the Australian Pesticides and Veterinary Medicines Authority (APVMA) concluded that it was unlikely that amisulbrom would lead to significant carcinogenic risks for humans as the tumours seen in animal tests were formed at unrealistically high doses.

3.8. The applicant described what clubroot was and how it affected the brassica plant. The applicant was unable to state how wide-spread the clubroot problem was and could not give definitive numbers on the amount of lost produce resulting from the disease. The applicant outlined that there were only a few treatments for clubroot available on the market, citing flusulfamide, fluazinam, calcium cyanamide (sold as a fertiliser but has fungicidal activity when converted into cyanamide) and lime as examples.

3.9. The applicant stated that for brassica treatment, the product could be applied in a farm setting but would normally be applied in nurseries by treating the plug of the brassica seedling. For potatoes, the applicant stated that the in-furrow spray was a targeted application method and gave an overview on this process.

3.10. The Committee asked the applicant how the drenching worked, as the description in the presentation appeared to differ from that in the application form and other accompanying material. The applicant responded by saying the drench would be applied over the tops of the brassica seedlings sitting in trays. The applicant further noted that enough of substance would only be applied to wet the plugs of

the seedlings. The committee asked follow up questions regarding recycling the substance and controlling the dose rates for seedlings. The applicant responded by stating that the substance had the potential to be collected and reused and that water rates would be adjusted to only wet the plugs and not produce excess water. The Committee also asked about the waste solution disposal process for brassica seedlings. The applicant responded by stating that it would likely be similar to current processes in nurseries using pesticide substances.

3.11. The Committee asked for further clarification regarding the treatment of potatoes by in-furrow spray. The applicant provided more information about this process. The Committee also asked for more information on the potato trials conducted by the applicant and asked when they would have a definitive application rate for in-furrow spraying. The applicant responded by stating that it was a challenge to find sites for powdery scab inoculation but noted in Australia the application rate was 20 to 25 g [of amisulbrom] per 100 metres which was lower than their current maximum application rate provided in the GAP table.

3.12. The Committee questioned the cost-effectiveness of AMICUS. The applicant responded by stating that on a per plant basis, AMICUS does have a comparatively low cost.

3.13. The Committee commented on the release of the science memorandum and asked why the applicant could not provide more information [in their application]. The applicant responded by stating that it was not their current practice but they could place a bit more information into the application in future. The applicant further stated that they were limited by the current application form.

3.14. The Committee asked if the substance would be another tool in the box [for growers] in terms of fungicide resistance. The applicant agreed.

3.15. There were no further questions.

EPA's presentation

3.16. Régis Lapage, Michael Berardozzi and Julian Jackson presented the EPA assessment, stating that the specific application methods proposed for AMICUS (drenching and in-furrow spray) were taken into account in the risk assessment and they also highlighted that the assessment on potatoes used the highest application rate as proposed by the applicant (at 2.5 kg amisulbrom/ha) as a worst-case scenario.

3.17. The EPA gave a brief description of the active ingredient, amisulbrom, outlining some of the jurisdictions where it had been approved, including Japan where it was first approved in 2008.

3.18. The EPA presented the hazardous properties and characteristics of amisulbrom. The active ingredient was classified as 6.4A (eye irritant), 6.7B (suspected human carcinogen) and 9.1A (very ecotoxic to the aquatic environment). The EPA also described the environmental fate data provided by the applicant, showing that amisulbrom was considered persistent in laboratory soil but not persistent under field conditions. It was also highly persistent in water, it had a low potential to bio-accumulate and it was considered to be immobile in soil. The EPA noted that they included the metabolite IT-4 in

their risk assessment as it was persistent in water and soil and was more toxic in soil than its parent, amisulbrom.

3.19. The EPA further explained their risk assessment methodology, examining the relevant exposure routes and noting that exposure by spray drift was reduced or nullified from the use of this substance due to the specific application methods. For human health, the EPA only considered the mixing and loading of the substance due to the modelling being only fit for purpose for wide-dispersive spray applications in the field. The EPA concluded that risks to operators were below the level of concern even without the use of Personal Protective Equipment (PPE) but the EPA still recommended that operators wore PPE when using pesticides. The EPA also stated that risks to re-entry workers and bystanders were below the level of concern.

3.20. The EPA described their consultation with WorkSafe, outlining that compliance with the HSW (HS) Regulations and Health and Safety at Work (General Risk and Workplace Management) Regulations would be adequate to reduce the risks associated with the use of this substance in the workplace but also noted that duties under sections 39 to 42 of the HSW Act may not have been met; this was due to AMICUS possessing a suspected carcinogenic (6.7B) classification.

3.21. The EPA then presented on the environmental risk assessment, announcing that they would only be covering the areas where refinement was necessary. The EPA briefly summarised that for groundwater, sediment-dwelling organisms, non-target plants, non-target arthropods and pollinators the risks were below the level of concern and no further refinement was necessary. Refinement was required for aquatic organisms, soil organisms and birds as risks were above the level of concern.

3.22. The EPA noted for the aquatic risk assessment, amisulbrom showed a high level of toxicity to aquatic organisms. For the formulated product, AMICUS, it was less toxic than amisulbrom but it was still considered ecotoxic. The risk assessment also took the metabolites of amisulbrom, IT-15 and IT-4, into consideration. The EPA risk assessment took into account spray drift and runoff in the field. For the drenching application for brassicas, spray drift modelling was not necessary but the EPA did consider runoff. For in-furrow spray for potatoes, the EPA considered both spray drift and runoff. The aquatic risk assessment concluded that no buffer zone was necessary to mitigate against runoff, having taken into consideration a 4% slope (for potatoes), and while the risk from spray drift was minimal due to the application methods, the EPA recommended some controls to limit application of AMICUS by drenching for vegetable brassicas and in-furrow application for potatoes to mitigate against any potential risks.

3.23. The EPA noted for the soil organisms risk assessment, the acute in-field risks, based on amisulbrom, could not be completely excluded for threatened or non-threatened species of soil mites and collembolans when AMICUS was used on potatoes. The EPA had no information to suggest that threatened species of soil mite and collembolan would inhabit agricultural fields and any effects would be limited to the portion of the field where the substance would be used (for potatoes) or the plugs planted (for the vegetable brassicas). The chronic in-field risks, based on amisulbrom and its

metabolite IT-4, could not be completely excluded for threatened species (ie earthworms). The EPA discussed that threatened earthworms were unlikely to be present in agricultural fields (in-field) based on information from Department of Conservation reports[2][3]. Overall, the EPA considered the acute and chronic in-field risks to be below the level of concern based on the weight of evidence. Off-field risks were considered irrelevant due to the application methods (ie lack of spray drift).

3.24. The EPA also discussed soil accumulation, particularly for the metabolite of amisulbrom, IT-4. This metabolite was modelled over a 20 year period and was found to present no risks to non-threatened species of earthworms but to present risks above the level of concern for threatened species of earthworms. The EPA commented that threatened species of earthworms were considered unlikely to be present in-field and the model assumed the same furrows would be used every year. Therefore, the overall risk was considered below the level of concern.

3.25. The EPA discussed their bird risk assessment. This assessment found chronic risks were above the level of concern for threatened and non-threatened species for both drenching and in-furrow application methods. After refinement, the EPA noted that no mortality was found in the bird toxicity studies at the highest dose rates tested. The EPA also noted that birds would be unlikely to gain all their food from the treated site and that potato fields would not likely be attractive to foraging birds. Amisulbrom was not considered systemic, therefore, it was unlikely that weed seeds or wild plants would be contaminated. The EPA found that overall, based on the weight of evidence, chronic risks to birds were considered to be negligible.

3.26. The EPA then described their proposed additional and varied controls for the substance, including the maximum application rates for both vegetable brassicas and potatoes, the restriction of application methods to drenching and in-furrow spray only and the maximum impurity permitted in the active ingredient, amisulbrom.

3.27. The EPA presented their findings for the cultural risk assessment and concluded that AMICUS may impact the aquatic environment and affect mahinga kai (food sources) such as fish, crustacea and algae. It was noted that the substance contained a suspected carcinogen that could also impact taha hauora (human health and well-being) – due to their high representation in cancer-related conditions, Māori could be disproportionately affected. Overall, the EPA concluded that the proposed controls would adequately manage the risks to Māori and no issues arose concerning the Treaty of Waitangi.

3.28. The EPA discussed the benefits of AMICUS proposed by the applicant, including its low risk and cost effectiveness. The EPA noted that AMICUS may have a lower hazard classification than other similar substances while stating that substances should not be compared on the sole basis of their classification. The EPA did not receive any information on the cost effectiveness of AMICUS. The EPA were unable to discuss resistance management of the substance as this would be covered by ACVM.

[2] Townsend, A.J.; de Lange, P.J.; Duffy, C.A.J.; Miskelly, C.M.; Molloy, J.; Norton, D.A. 2008: New Zealand Threat Classification System manual. Department of Conservation, Wellington. 35 p.

[3] Buckley, T.R.; Boyer, S.; Bartlam, S.; Hitchmough, R.; Rolfe, J.; Stringer, I. 2015: Conservation status of New Zealand earthworms, 2014. New Zealand Threat Classification Series 10. Department of Conservation, Wellington. 10 p.

The EPA also noted that AMICUS contained a new active ingredient which was considered to be a significant benefit by the EPA.

3.29. The Committee asked the EPA for clarification on difference between the persistence [of amisulbrom] in the water environment data and rapid aqueous photolysis data submitted by the applicant. The EPA responded by stating that the difference in degradation rates could be explained by the different studies, ie the water sediment studies (for persistence) are carried out in the dark, removing photolysis from the equation. The comparison is a theoretical biological degradation process versus a chemical degradation process through photolysis.

3.30. The Committee asked why the EPA Staff Report stated that the substance was for import and manufacture even though the application states the substance will not be manufactured. The EPA responded by saying that [if approved] the manufacture of the substance would also be covered under the Hazardous Substances and New Organisms (HSNO) Act. The Committee also asked whether the name will be approved under AMICUS or AmiShield after the applicant announced the name change. The EPA responded by stating that the applicant would likely need to register the trade name with ACVM and that the EPA approves substances and not the name under the HSNO Act.

3.31. The Committee asked for clarification on the soil accumulation model [for metabolite IT-4] shown in the presentation. The graph did not show any cumulative increase of the substance over time. The EPA responded by stating that the substance would break down, therefore, the remaining background level was drastically reduced throughout the year. The EPA further stated that a plateau is typically reached in three to four years.

3.32. The Committee stated that in the modelling, the same furrows [for potatoes] were used each year and asked if this would normally be the case. The EPA responded by saying they were unaware whether this would generally be the case and wanted some clarification from the applicant but concluded that it was a worst-case assumption.

3.33. Ngāi Tahu HSNO Kōmiti ("Ngāi Tahu") commented that they were unaware that the application would cover both importation and manufacture and asked whether that was common practice for most applications under the HSNO Act. The EPA responded by stating that there was no distinction between import and manufacture under the HSNO Act irrespective of the intention of the applicant and referenced section 28 of the HSNO Act.

3.34. There were no further questions.

Presentations by submitters

Ngāi Tahu HSNO Kōmiti

3.35. Stephanie Dijkstra from Ngāi Tahu began with a brief introduction of Ngāi Tahu and why they submit on EPA matters. She highlighted that Ngāi Tahu's takiwā (tribal territory) is diverse in the type of land it includes, which covers up to 70% of the South Island (totalling 40% of New Zealand).

3.36. Ngāi Tahu expressed concern over the chemical burden from introducing another chemical into New Zealand, stating that new chemicals should only be introduced when there is sufficient environmental benefit or as a replacement for an existing chemical of higher toxicity.

3.37. Ngāi Tahu expressed concern over potential spray drift and runoff, as well as the lack of buffer zone control for the substance, especially for the in-furrow spray method for potatoes. Ngāi Tahu also highlighted their concerns over the aquatic toxicity of the substance and the impact it could also have on organisms inhabiting riparian margins and drains, particularly as the planting period for potato crops coincided with the highest rainfall period of the calendar year which could lead to runoff.

3.38. Ngāi Tahu did not agree with the EPA's use of a 4% slope in their modelling of runoff for the potato crops as, in their experience, these crops may be present on slopes steeper than 4%. The Southland region was given as an example.

3.39. Ngāi Tahu also noted the lack of data made publicly available by the applicant prior to the submission process and did not feel toxicological information should have been in the confidential appendix, especially when it was already published elsewhere. Ngāi Tahu stated that by not having this confidential information, it does not allow for full engagement with Māori.

3.40. In concluding their presentation, Ngāi Tahu stated that they understood that the substance could be another tool for growers to utilise but did not believe that there were enough benefits of AMICUS given the increase of potential chemical burden on the environment. As such, they opposed the AMICUS application for release.

3.41. The Committee asked Ngāi Tahu to confirm what they meant when they talked about the "environmental benefits" of a new chemical and asked if they were referring to a wider definition incorporating environmental, social and economic benefits. Ngāi Tahu responded by saying they looked at the wider definition and that they believed that an economic benefit or an increase of yield by a certain percentage was not enough of a benefit. For AMICUS, Ngāi Tahu reiterated that they did not believe the substance balanced the environmental risk sufficiently with proposed controls.

3.42. The EPA commented that they continue to strive to improve the risk assessment methodology and processes to give a better understanding on how information is assessed in order to address some of the concerns Ngāi Tahu had regarding the lack of publically available information for the application.

3.43. There were no further questions.

Vegetable Research and Innovation Board

3.44. Dr Sally Anderson from Vegetable Research and Innovation Board ("Vegetable Board") began with an introduction to the Vegetable Board and the five groups they represent: Onions New Zealand, Tomatoes New Zealand, Process Vegetables New Zealand, the Buttercup and Squash Council and Vegetables New Zealand.

3.45. The Vegetable Board gave an overview on how clubroot affects brassica crops and stated that there were limited options for its treatment. The Vegetable Board briefly discussed the economic benefits of

brassicas to New Zealand (ie cabbage, broccoli and cauliflower), stating that these crops (not including forage brassica) were valued at over $NZ 82 million to New Zealand annually. They also stated there was only one other fungicide available for New Zealand growers and the new active ingredient would help with resistance management.

3.46. The Vegetable Board concluded their presentation stating that they supported the introduction of AMICUS to New Zealand.

3.47. The Committee asked whether the Vegetable Board's position would reflect that of the potato sector being that they are all in the same industry. The Vegetable Board replied by stating that the potato sector were not part of the Vegetable Board but they would imagine potato growers would support a different active [ingredient] in New Zealand.

3.48. There were no further questions.

Applicant's right of reply

3.49. The applicant stated that they were comfortable with the classification and controls set by the EPA and believed that the substance could be used with minimal risks. The applicant also stated that soil diseases are difficult to control and effective options were important. They also highlighted that brassica growers were eager to add a new tool to their tool kit [to control clubroot] and noted that they had recent demand from potato growers to start using this product, AMICUS. The applicant noted that they will strive to improve on the information made available to the public on their application form.

3.50. There were no further questions from the Committee, the EPA or other submitters.

3.51. The hearing was adjourned.

4. Consideration

4.1. The application was considered by the Committee on 31 July 2020, following the decision pathway (available in Appendix B).

4.2. The following information was considered by the Committee:

- the submissions;
- the Science Memorandum;
- the Staff Report;
- the WorkSafe assessment report;
- the Cultural Risk Assessment;
- information presented at the hearing.

4.3. 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

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

Table 1: Hazard classifications of AMICUS

Hazard	Applicant classification	EPA classification
Acute toxicity (oral)	**6.1D**	**No**
Acute toxicity (inhalation)	**6.1D**	**No**
Carcinogenicity	**No**	**6.7B**
Aquatic ecotoxicity	9.1A	9.1A
Soil ecotoxicity	**9.2D**	**No**

Risk assessment

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

4.6. 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.

4.7. The overall risk and benefit assessment:

- considered the risks posed by AMICUS;
- determined whether the risks outweighed 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.

Risks during importation, manufacture, transportation, storage and disposal

4.8. The applicant intends to import AMICUS into New Zealand in 100 to 200 kg bulk containers. Repackaging and relabelling will be carried out in New Zealand in a dedicated agricultural chemical facility. The risks associated with the importation, transportation, storage and disposal of AMICUS were considered by the Committee based on the EPA risk assessment.

4.9. 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

importation, transportation, storage and disposal of AMICUS would be negligible. These requirements 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

4.10. The Committee noted that the quantitative risk assessment determined that the risks to operators during the mixing and loading of AMICUS was acceptable even without the use of PPE. Although the quantitative risk assessment indicated that PPE was not required, PPE was still recommended for operators when using the substance. It was also determined that there was no need to set a re-entry interval control for workers, or a buffer zone to protect bystanders.

4.11. The Committee noted that WorkSafe assessed the available information for AMICUS 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

4.12. The Committee noted that the EPA had conducted a quantitative risk assessment. The risk assessment considered the effect of the proposed use of AMICUS on target and non-target organisms in the environment. Full details can be found in the Science Memorandum.

Aquatic organisms

4.13. The Committee considered that spray drift was not a relevant exposure route for the application of AMICUS as the substance is applied as a drench (for vegetable brassicas) or in-furrow (for potatoes). Runoff was therefore considered the only relevant environmental pathway. The EPA runoff risk assessment showed that predicted exposure concentrations of amisulbrom, applied as the formulated product AMICUS, to potatoes resulted in calculated risk quotients above the level of concern for acute risks to threatened species of fish and aquatic invertebrates, and chronic risks to threatened species of aquatic invertebrates. A set of controls have been proposed to ensure that risks to aquatic organisms will be under the level of concern, and with these controls in place, no buffer zone was determined to be necessary.

Groundwater

4.14. The Committee noted that for the active ingredient amisulbrom, the concentration was below the 0.1 µg/L trigger level set by the European regulators. Therefore, the risks were considered below the level of concern.

Sediment-dwelling organisms

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

Earthworms and other soil organisms

4.16. The Committee noted that the EPA assessment found that users were expected to apply AMICUS either by drench application (vegetable brassicas) or by in-furrow application methods (potatoes), therefore, it was likely that soil organisms would be exposed to the substance through the substance reaching the soil.

4.17. The Committee noted that acute and chronic risks to soil macro-organisms following the application of AMICUS to transplanted vegetable brassicas and potatoes were considered below the level of concern. No long-term risk from accumulation of the major metabolite IT-4 was identified. For soil microorganisms, risks were below the level of concern for vegetable brassicas, and although risks were unknown at the maximum proposed application rate for potatoes, any impacts would be limited to the furrows. No risks were anticipated between furrows, provided that the proposed controls were complied with.

Non-target plants

4.18. The Committee noted that no quantitative risk assessment was performed for non-target plants. Risks to non-target plants following the use of AMICUS were considered negligible due to the specific application methods used for treatment of vegetable brassicas and in-furrow spraying to potatoes.

Birds

4.19. The Committee noted that for applications to potatoes and vegetable brassicas, the bird screening risk assessment identified chronic risks potentially above the level of concern (to non-threatened and threatened species of birds for applications to potatoes, and to threatened species of birds for applications to vegetable brassicas), following the use of AMICUS, therefore, some refinement was necessary.

4.20. After refinement at Tier 1, potential chronic risks were still above the level of concern for all focal species following applications to potatoes (both non-threatened and threatened), and one focal species following applications to vegetable brassicas (threatened species only). However, after further refinement, considering the conservatism of the chronic toxicity endpoint, the high likelihood that birds will forage and therefore obtain a proportion of their diet from other (non-treated) areas, and the unattractiveness of potato fields generally as a food source for birds, the chronic risks identified for birds following the application of AMICUS to potatoes and vegetable brassicas, were considered negligible.

4.21. The Committee also noted that the risk from secondary poisoning was considered to be low.

Pollinators and non-target arthropods

4.22. The Committee noted that no quantitative risk assessment was performed for pollinators and non-target arthropods. Risks to pollinators and non-target arthropods following the use of AMICUS were considered negligible due to the specific application methods used for treatment of vegetable brassicas and in-furrow spraying to potatoes, which minimised the route of exposure to pollinators and non-target arthropods.

Assessment of risks to Māori and their relationship to the environment

4.23. 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 AMICUS on kaitiakitanga, and fulfilment of Treaty of Waitangi obligations.

4.24. Based on the Māori perspective report and other information provided to the Committee by the applicant and submitters, the Committee considered that with the proposed controls in place, the impact of approval of use of AMICUS 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 to risks to society, the community and the market economy

4.25. 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

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

Assessment of benefits

4.27. The applicant referred to several benefits of the substance in their application and elaborated on these at the hearing.

More choice for growers

4.28. The applicant considered that the approval of AMICUS could provide more choice for growers to control clubroot in brassicas, thereby reducing the pressure associated with potential resistance developing with existing control agents (the applicant noted that there were four other substances available for the control of clubroot). The EPA noted that AMICUS contains a new active ingredient which could provide an additional tool for growers. This was considered a **significant benefit.**

Low risk and cost effective

4.29. The applicant stated that AMICUS was a low risk and cost effective tool. The EPA received no information on the cost effectiveness of AMICUS. The EPA noted that AMICUS may have a lower hazard classification than other substances used to control clubroot in brassica and powdery scab on

potatoes, however, it is classified as a suspected human carcinogen (6.7B). While substances should not be compared on the sole basis of their classification, it is noted that amisulbrom does not have any acute toxicity classification (class 6.1) compared to other active ingredients already available on the market with a similar use pattern (eg flusulfamide and fluazinam). These active ingredients have chronic classifications (6.9A and 6.9B, respectively) and are also classified as suspected reproductive or developmental toxicants (6.8B). Therefore, it is likely that the use of AMICUS would be associated with lower acute risks compared to other substances with similar use patterns.

4.30. It is considered that the availability of AMICUS would provide economic benefits for some businesses with the potential for flow-on effects to local communities and the New Zealand economy, including additional consumer choice and greater market competition.

Conclusions on the assessment of benefits

4.31. 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 AMICUS.

5. Controls

5.1. The suite of controls proposed by the EPA include the prescribed controls triggered by the hazard classifications of AMICUS, 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 accepted these controls for AMICUS.

Prescribed controls

5.2. The hazard classifications of AMICUS 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.

5.3. 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 Appendix A.

5.4. The Hazardous Substances Labelling, Safety Data Sheet (SDS), Packaging, Disposal and Hazardous Property Controls (HPC) Notices Part 1, Part 3, Part 4A, Part 4B and Part 4C 2017 apply to AMICUS.

5.5. 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 that 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. At least one component of AMICUS has a Workplace Exposure Value (WES) that needs to be identified on the SDS.

Exposure limits

5.6. The Committee noted that the EPA has not set a Tolerable Exposure Limit (TEL) for AMICUS, or any element or compound in the substance, as exposure to this substance is not likely to result in an appreciable toxic effect to people, provided controls on use are followed.

5.7. Acceptable Daily Exposure (ADE) and Potential Daily Exposure (PDE) shown below are provided 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.

5.8. The following values have been provided for amisulbrom:

- ADE = 0.12 mg/kg bw/day;
- PDE (food) = 0.084 mg/kg bw/day;
- PDE (drinking water) = 0.014 mg/kg bw/day;
- PDE (other) = 0.012 mg/kg bw/day.

5.9. No Environmental Exposure Limit (EEL) values are proposed at this time for amisulbrom. 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.

5.10. There is a Workplace Exposure Standard (WES) value currently set for at least one component of AMICUS but, as it is not a Prescribed Exposure Standard (PES) value, it is a guidance value used for the management of health risks. No PES has been set for any component of AMICUS.

Changes to prescribed controls

5.11. It is considered that the prescribed controls will manage most of the risks to humans and the environment. However, additional controls are recommended to be set, and default controls varied, to mitigate the non-negligible risks to the environment.

5.12. The following modifications and additions to the EPA Notice controls apply to this substance under sections 77 and 77A of the HSNO Act to manage the risks of use of AMICUS.

Application rates

5.13. Significant environmental risks may occur from the use of this substance, due to the hazards posed by amisulbrom, the active ingredient in AMICUS. Therefore, it is considered necessary to set a maximum application rate, number of applications and frequency.

5.14. The maximum application rate for vegetable brassicas is 0.7 kg amisulbrom/ha (equivalent to 1.4 kg AMICUS/ha), with a maximum of one application per year.

5.15. The maximum application rate for potatoes is 2.5 kg amisulbrom/ha (equivalent to 5.0 kg AMICUS/ha), with a maximum of one application per year.

Application methods

5.16. The environmental risk assessment was based on the application methods specified by the applicant. In particular, the restriction to apply AMICUS via ground-based methods only (drench or in-furrow application), and the restriction to favourable wind conditions are key factors in minimizing exposure to aquatic environments.

5.17. AMICUS must only be applied by ground-based methods.

5.18. AMICUS must be applied with specific application equipment, with application limited to drench application for vegetable brassicas and in-furrow application for potatoes.

5.19. AMICUS 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.

Labelling

5.20. In order to limit off-target exposure, the label must include the following 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*."

Maximum impurity

5.21. An impurity limit for the metabolite 3-bromo-6-fluoro-2-methyl-1-(1H-1,2,4-triazol-3-ylsulfonyl)-1H-indole ('IT-4') has been identified by the EU: maximum 2 g/kg.

5.22. This is considered a toxicologically relevant impurity and therefore the EPA sets a control to limit the maximum amount of this metabolite.

Review of additional controls and variations

5.23. 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 AMICUS in New Zealand.

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

5.25. At the hearing, the applicant was given an opportunity to comment on the proposed controls as set out in the Staff Report. 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. Taking into account the assessment of the potential risks and benefits associated with AMICUS 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 AMICUS will be negligible;
- significant adverse effects on the social or economic environment or international obligations from the use of AMICUS are not anticipated;
- if AMICUS is applied in the proposed manner, it would likely be consistent with the principles of Te Tiriti o Waitangi (the Treaty of Waitangi). Significant adverse effects on the relationship of Māori and their culture and traditions with their environment and taonga, including culturally significant species, resources, and places, and the customary values, practices and uses associated with these taonga have not been identified;
- Benefits will be derived for New Zealand by allowing the use of AMICUS.

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 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.

7.2. 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 AMICUS 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 Ngaire Philips**	Date: **7 September 2020**
Chair, Decision Making Committee, **Environmental Protection Authority**	

Appendix A: Controls applying to AMICUS

EPA Controls

Control code	Notice	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 77A	When used on vegetable brassicas, the maximum application rate is 0.7 kg amisulbrom/ha (equivalent to 1.4 kg AMICUS/ha), with a maximum of one application per year. When applied on potatoes, the maximum application rate is 2.5 kg amisulbrom/ha (equivalent to 5 kg AMICUS/ha), with a maximum of one application per year.
Application method	Section 77A	AMICUS can only be applied by ground-based methods. AMICUS must be applied with specific application equipment, application is limited to drench application for vegetable brassicas and in-furrow application for potatoes. AMICUS 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.
Label	Section 77 variation to Labelling Notice	The substance label must include the following statement, or words to the same effect: *"**DO NOT** apply when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site".*
Maximum impurity	Section 77A	The following limit is set for a toxicologically relevant impurity in the active ingredient amisulbrom used to manufacture this substance: 3-bromo-6-fluoro-2-methyl-1-(1H-1,2,4-triazol-3-ylsulfonyl)-1H-indole: maximum 2 g/kg.

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.

Code	Regulation	Description	Extra information
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	No TEL is set at this time
HSW13-9	Reg 13.18	Duty of PCBU to ensure prescribed exposure standards for class 6 substances not exceeded	No PES is set at this time
HSW13-14	Reg 13.30 - 33	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	

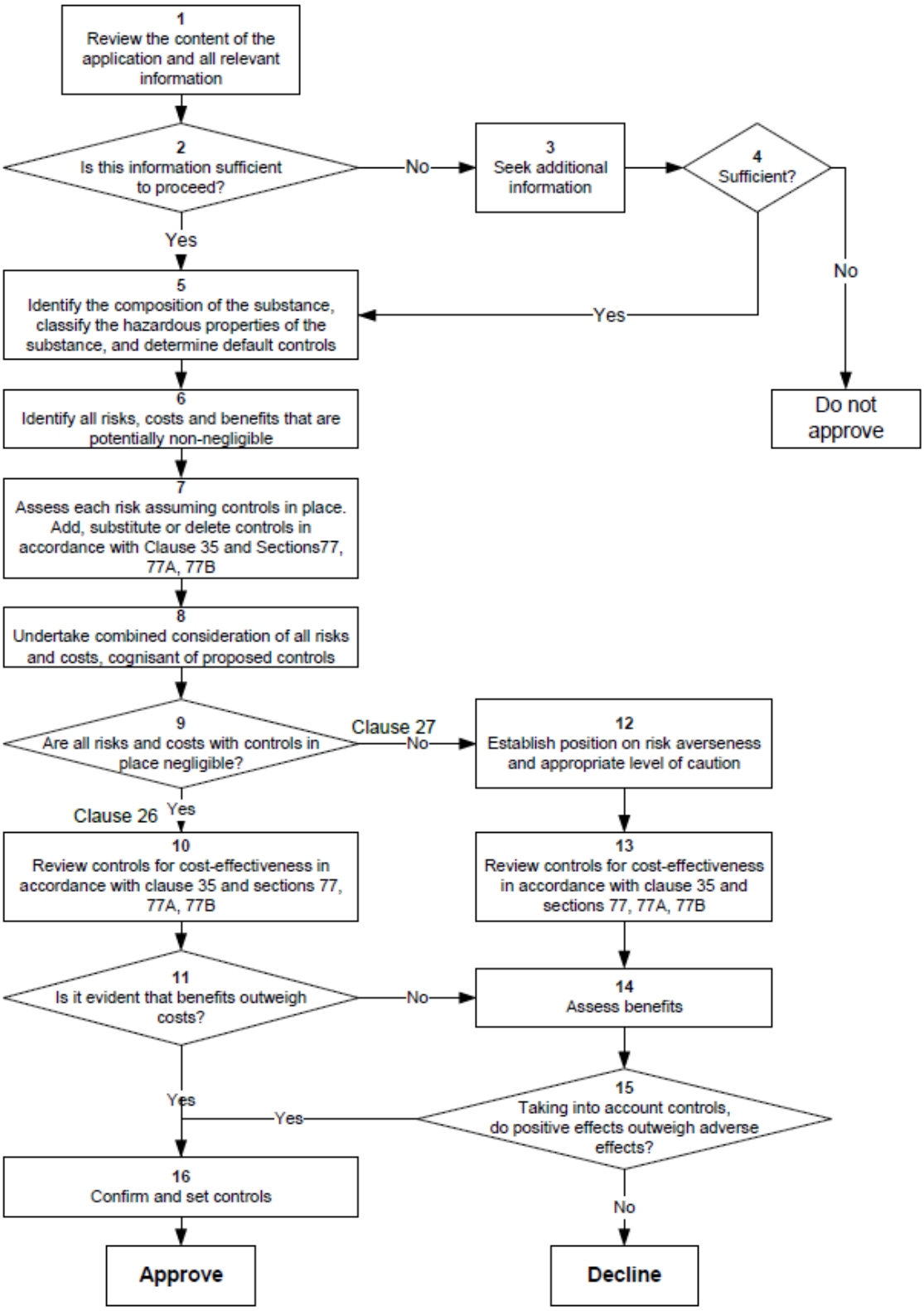
Appendix B: Decision Path

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[4]** 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).

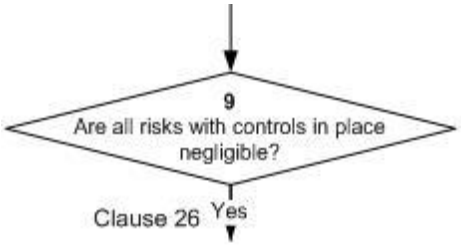
[4] Relevant effects are **marginal effects**, or the changes that will occur as a result of the substance being available. Financial costs associated with preparing and submitting an application are not marginal effects and are not effects of the substance(s) and are therefore not taken into account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

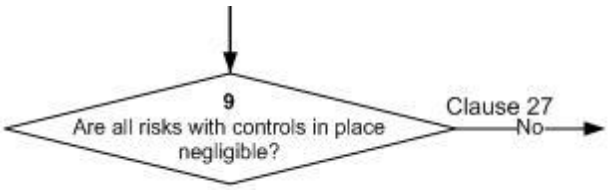
	Step 1:	Identify all possible risks and costs (adverse effects) and benefits (positive effects) associated with the approval of the substance(s), and based on the range of areas of impact described in clause 9 of the Methodology and sections 5 and 6 of the Act[5]. Consider the effects of the substance 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[6], 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[7].

[5] 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.

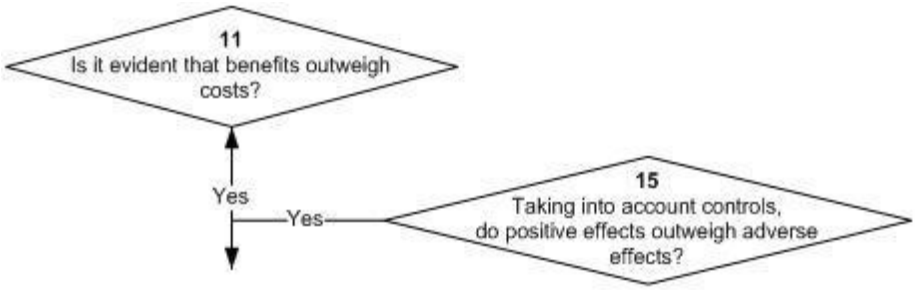
[6] Negligible effects are defined in the Annotated Methodology as "Risks which are of such little significance in terms of their likelihood and effect that they do not require active management and/or after the application of risk management can be justified by very small levels of benefits".

[7] 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[8]. 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.

[8] 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[9]. 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.

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