Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

17 April 2019

Overview

Substance	Exirel
Application code	APP203558
Application type	To reassess any hazardous substance under section 63A of the Hazardous Substances and New Organisms Act (HSNO Act; "the Act")
Applicant	FMC New Zealand Limited (FMC)
Purpose of the application	FMC has requested that the approval for Exirel be changed in the following areas: application method (that is, include helicopter aerial application); buffer zones; labelling statements; benefits
Submissions received	New Zealand Agricultural Aviation Association Te Rūnanga o Ngāi Tahu Apiculture New Zealand New Zealand Beekeeping Incorporated The Soil & Health Association of New Zealand
Considered by	A Decision-Making Committee of the Environmental Protection Authority
Decision	Modified reassessment approved
Approval code	HSR100857
Hazard classifications	6.3A, 6.5B, 6.9B, 9.1A, 9.4B

Application dates	
Date application received	23 August 2018
Submission period	6 September 2018 – 18 October 2018
Hearing date	12 December 2018 – 14 March 2019
Consideration date	14 March 2019
Date decision signed	17 April 2019

Executive summary

Exirel insecticide is a suspo-emulsion containing 10.6 % cyantraniliprole, and other components. It was approved under the Act on 28 June 2013. It is used as an insecticide on fodder brassicas such as turnips, swede, forage rape and kale, and is currently applied by ground-based application methods[1].

The application to modify the existing approval for Exirel was made by FMC and was publicly notified in accordance with section 53 of the Act.

During the submission period, five submissions were received on the application. Two submissions expressed their support to this application: one from the New Zealand Agricultural Aviation Association (NZAAA) and one from Te Rūnanga o Ngāi Tahu. The submission from Apiculture New Zealand was neutral. The submissions from New Zealand Beekeeping Incorporated and The Soil & Health Association of New Zealand opposed the application.

All submitters requested to speak at the hearing though Ngāi Tahu wished to be heard only in the case where a public hearing was requested by others. The Soil & Health Association later withdrew their wish to be heard. On 12 December 2018, a hearing was held in Wellington. The applicant presented at the hearing in support of the approval of the application and verbal submissions were heard from the NZAAA, Apiculture New Zealand, and New Zealand Beekeeping Incorporated.

The hearing was adjourned to allow further time for submitters to comment on information provided in response to a Point of Order raised by Apiculture New Zealand. No further information was received.

After considering all relevant information available following the adjournment, the Decision-Making Committee ('the Committee') decided that it had sufficient information for making a decision.

The Committee assessed the risks posed by Exirel and determined that they would be negligible with controls. The Committee assessed the benefits associated with the aerial application of Exirel and determined that they would be non-negligible. In accordance with section 29(1)(a) of the Act, the Committee considered the positive effects of the substance outweigh the adverse effects and decided to approve the application to allow the aerial application of Exirel with controls.

[1] Ground-based methods of applying pesticides include, but are not limited to, application by ground boom, airblast or knapsack, and do not include aerial application methods.

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1 Background

1.1 Exirel insecticide is a suspo-emulsion containing 10.6% cyantraniliprole, and other components. It is used as an insecticide on fodder brassicas such as turnips, swede, forage rape and kale and is currently applied by ground-based application methods[2].

1.2 The substance, called "DuPont Exirel Insecticide" at that time, was approved on 28 June 2013 (application number APP201204; approval reference HSR100857). The original application also included another substance called DuPont Benevia Insecticide, which also contained cyantraniliprole and received a similar suite of controls to those for Exirel. These were the first approvals in New Zealand of substances containing the active ingredient cyantraniliprole.

1.3 The original applicant for Exirel, DuPont New Zealand Limited (DuPont), previously applied to have the ground-based only restriction lifted. Grounds for reassessment were approved in 2015 (APP202669) because adding aerial application methods was considered, at that time, to be a significant change of use. A modified reassessment was subsequently performed in 2016 (APP202774).

1.4 Advice by the Environmental Protection Authority (EPA) to the Committee in 2016, following a quantitative risk assessment of the ground-based and aerial application methods, was that the benefits of Exirel applied aerially outweighed the risks. The Committee, however, considered that, based on the information provided in the application and at the hearing, the benefits of aerial application were negligible. They also considered that there were uncertainties over appropriate buffer zone distances to protect aquatic life. As the Committee considered that the risks were non-negligible and the benefits negligible, they declined the modified reassessment and the original approval from 2013 remained unchanged.

1.5 DuPont applied for grounds for a reassessment of Exirel again in 2017. Grounds were approved based on significant new information relating to the benefits of the substance, including information related to integrated pest management and spraying from a helicopter.

1.6 After FMC Corporation acquired a significant portion of DuPont's Crop Protection business (including Exirel) in November 2017, Cheminova (NZ) Ltd (a wholly owned subsidiary of FMC Corporation and now operating as FMC New Zealand Limited, "FMC") applied for the reassessment of Exirel.

2 Process, consultation and notification

Lodgement and formal receipt

2.1 The FMC reassessment application was lodged on 5 February 2018. It was formally received on 24 August 2018. In their application to reassess Exirel, FMC requested that the approval for Exirel be changed in the following areas:

- application method (that is, include helicopter aerial application)
- buffer zones
- labelling statements
- benefits.

[2] Ground-based methods of applying pesticides include, but are not limited to, application by ground boom, airblast or knapsack, and exclude aerial application methods.

Scope of application

2.2 The EPA's Chief Executive considered the content of the application and decided to use the EPA's discretionary power in section 63A(1) of the Act to proceed with the application as a modified reassessment. It was decided that the scope of the modified reassessment would be limited to an assessment of:

- application method
- buffer zones
- labelling statements
- benefits.

Notification of application

2.3 The Ministry for the Environment, the Ministry of Health, the Agricultural Compounds and Veterinary Medicines (ACVM) group of the Ministry for Primary Industries, the Department of Conservation, and Fire and Emergency New Zealand (FENZ) were advised of the application and notified of the submission period. FENZ was the only agency to respond: "we have no issue with this type of change so will not make a submission in this case." WorkSafe New Zealand ("WorkSafe") provided email comments on this application[3].

2.4 The General Manager Hazardous Substances and New Organisms decided not to use the EPA's discretionary power in section 63A(4) of the Act to target the consultation on this application, and it was publicly notified in accordance with section 53 of the Act.

2.5 The application was opened for submissions from 6 September 2018 to 18 October 2018.

Submissions received

2.6 Five submissions were received for this application. Two submissions expressed their support to this application: one from the New Zealand Agricultural Aviation Association and one from Te Rūnanga o Ngāi Tahu. The submission from Apiculture New Zealand was neutral. The submissions from New Zealand Beekeeping Incorporated and The Soil & Health Association of New Zealand sought that the application should not be approved. All submitters requested to speak at the hearing though Ngāi Tahu wished to be heard only in the case where a public hearing was requested by others. The Soil & Health Association later withdrew their wish to be heard.

2.7 The New Zealand Agricultural Aviation Association (NZAAA) considered that aerial applications have a number of advantages over ground-based applications, especially in steeper and more difficult country and when ground conditions are very wet. Ngāi Tahu welcomed that "Māori issues are being taken seriously by an applicant and that [their] concerns have been addressed." Their concern was particularly on buffer zones. The other submitters generally raised concerns on the controls in place, particularly those protecting bees and those on the buffer zones.

2.8 The Committee took account of these submissions in making its decision and noted that the EPA Staff Report responded to these issues.

[3] See https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP203558/APP203558-Work-Safe-comments.pdf

3 The EPA Staff Report

3.1 The Staff Report is the EPA review of the application and available data regarding the substance. It provides information to assist the Committee to make its decision. The EPA considered that the previous EPA risk assessments on the aerial use of Exirel made in 2016 remained relevant for this reassessment.

3.2 The only assessment updated as part of this evaluation was for the risks from aerial use on the aquatic environment. This updated assessment used refined toxicological values.

3.3 Confidential information was provided by the applicant, which was taken into account during the assessment of Exirel. The confidential information was letters of support received by the applicant.

3.4 The previous risk assessment on the aerial use of Exirel found that the risks to operators, re-entry workers, and bystanders were all negligible; and WorkSafe New Zealand agreed. The previous risk assessment on the aerial use of Exirel also found that the risks to soil organisms, non-target plants, sediment-dwelling organisms, and birds were all negligible. The impact on beneficial arthropods was mixed.

3.5 The Staff Report stated that the risks to the aquatic environment were negligible. The assessment considered that buffer zones were not needed, though the cultural assessment welcomed the 50 m buffer zone volunteered by FMC and Māori acceptance (including Ngāi Tahu) was based on the inclusion of that buffer zone.

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

3.7 The Staff Report concluded the proposed use of Exirel results in negligible risks to human health and the environment, when appropriate controls are in place and followed and that the potential benefits were significant and non-negligible. The EPA suggested that the overall level of benefit provided by the possibility of aerial application of Exirel would outweigh the adverse effects, with the implementation of the identified changes to control.

4 Hearing

4.1 On 12 December 2018, a hearing was held at AREA Events in Wellington. Presentations were given by the applicant, the EPA and three submitters.

Point of order

4.2 Apiculture New Zealand Inc. shared a point of order with the Committee Chair on Monday 10 December 2018. The Chair advised that the Committee would consider the point of order but needed to consult with those who had provided the content. There was insufficient time before the hearing to consider this request. The Chair specified that everyone at the Hearing receive a copy of the point of order from Apiculture New Zealand.

4.3 The decision about this point was released after the hearing. The result of the point of order is discussed further in paragraph 4.57.

Applicant's presentation

4.4 The Exirel application was presented by representatives from FMC.

4.5 They began by giving an overview of the situation and the reasons for this application. They presented the importance of forage brassica crops in New Zealand which represents the single largest annual crop in New Zealand with 350,000 – 400,000 ha grown annually and an estimated value of $1.3 billion annually, that is 3,700 – 4,000 $/ha. They also indicated that the brassica crops are consumed by stock in the field before the flowering stage.

4.6 They then spoke about the benefits of using Exirel, and of aerial application. They mentioned that the original applicant for Exirel, DuPont (New Zealand) Limited, started a research programme on Integrated Pest Management (IPM) in 2014 in order to address issues with pests becoming resistant to synthetic pyrethroid and organophosphate insecticides. The programme's third report showed there were cultural, economic and environmental benefits of introducing IPM, and Exirel is an effective tool in IPM programmes. They estimated that if aerial application was approved for Exirel, it would lead to a 60 $/ha benefit to growers in New Zealand. FMC has received a lot of letters of support regarding this application.

4.7 FMC clarified that the proposed use pattern for Exirel is ground-based and by aerial application. Both would have an application rate of 15 g ai/ha[4] with the same frequency (minimum interval of 14 days). The aerial application would only be made by helicopter, and only if no rain is expected.

4.8 They congratulated the EPA on their risk assessment work and summarised it. They underlined that the report concluded aerial application does not increase the risk for human health and, given that Exirel is sprayed before brassicas flower, there was no risk to bees.

4.9 They continued by proposing an additional label statement to include "toxic to terrestrial invertebrates, including bees", with a special part on bee safety. They compared it to other bee statements on overseas labels.

4.10 FMC emphasized that the EPA Staff Report said buffer zones were not required but FMC proposes to set a 50 m buffer zone, based on discussion with Ngāi Tahu and the generic requirements of various regional councils.

4.11 They then detailed the reasons why aerial application was required. In particular, the use of Exirel by aerial application would allow older chemistry to be replaced with a less toxic and more selective product, reduce the number of applications required, limit crop damage, help farmers adopt IPM methodology, and enable them to work quickly and safely in wet conditions and hill country.

4.12 FMC continued by promoting the benefits of using Exirel compared with other competitive products, due to its lower hazard classification for the worker and for the environment. They stated that use of Exirel can also improve the financial performance of forage brassica crops while using an IPM methodology.

4.13 FMC finished by comparing tractor and helicopter safety. They concluded that aerial applications are not more dangerous than ground-based applications, and that the overall benefits of aerial application for Exirel outweigh any additional risks.

4.14 The Committee asked the applicant how many reports FMC has on bee toxicity incidents. The applicant responded there were no reports on bee toxicity accidents in Australia and New Zealand for Exirel. The Committee indicated the application rate in the European Union (EU) is fixed to 20 g ai/ha during flowering. The applicant responded that even with this application rate and one or two applications during flowering, the EU authorities concluded there was a low risk

[4] 15 g ai/ha means that 15 grams of the active ingredient will be distributed per hectare treated

for bees. They continued that as the application rate is lower in New Zealand and the applications would be when the crop is not flowering, the risk should be negligible for bees.

4.15 The Committee questioned the numbers given on aerial accidents by saying tractors were used a lot more on farms than helicopters which can explain the smaller number of accidents by helicopter. The applicant replied there were not a lot of statistics available but considered there was no increase in the risk when moving from ground-based to aerial application.

4.16 The Committee asked for clarification around the benefits the applicant presented. The applicant explained the value of the crop is assessed as dry matter yield. For forage brassicas, annual production is 15,000 kg dry matter/ha. The crop is traded or sold at 25 cents/kg, so they evaluated its value to the grower to be between 3,700 and 4,000 $/ha. The 60 $/ha benefit is derived from estimated increases in yield and reductions in the cost of insecticides required if Exirel could be aerially applied as part of an IPM programme. They assessed the benefit from ground-based application of Exirel to be $2 million. They estimated that the benefit with aerial applications would be over $10 million.

4.17 In addition, the Committee asked for clarification around the proposed buffer zones, noting that the EPA does not recommend a buffer zone and the applicant proposes one of 50 m. The Committee wondered if the buffer zone proposed lies between the target crop and water bodies, or between the target crop and other crops outside the treatment area. The applicant responded that the 50 m buffer zones are required by almost every regional council, and that the proposed 50 m buffer zone is between the treated crop and another flowering crop (like clover for example) or plants or other crops like cereals.

4.18 EPA staff asked the applicant to confirm that the current ground-based application rate was 15 g ai/ha. The applicant confirmed it was, and that this was the rate being requested for aerial applications.

4.19 New Zealand Beekeeping Incorporated asked if a 50 m buffer zone means no product is applied on the 50 m buffer zone if a flowering crop were adjacent to the brassica crop. The applicant confirmed that no product must be applied on the 50 m buffer zone.

4.20 Apiculture New Zealand expressed doubts on the definition of the buffer zone. The applicant answered it would probably be a downwind buffer zone but the EPA needs to clarify this point.

4.21 Apiculture New Zealand expressed concern about the controls given that Exirel is classified as 6.3A (skin irritant). The applicant acknowledged that and indicated the label currently says to wear waterproof gloves, overalls and footwear but the label instruction will be improved.

4.22 In addition, Apiculture New Zealand asked for the definition of suspo-emulsion, surfactants and if some tests with surfactants have been conducted on bees since 2014. The applicant answered that the Exirel formulations were chosen for their stability and their ability to mix easily in water. The applicant confirmed they have not conducted additional tests on bees with surfactants since 2014.

EPA presentation

4.23 EPA staff presented their Staff Report, including a brief history of the application. As this is the third evaluation of Exirel in five years, they explained that the EPA focussed its efforts on the area of concern in the previous reassessment; that is, the effect on the aquatic environment.

4.24 They pointed out that previous risk assessments concluded there was a negligible risk to operators, re-entry workers, bystanders, soil and sediment-dwelling organisms, non-target plants, birds and groundwater. The previous risk assessments identified a potential risk via diet

for bees and that bees should not be exposed to flowering plants. The results of risk assessments were mixed with regard to non-target arthropods, with potential or negligible risks depending on species.

4.25 EPA staff explained that the updated risk assessment focussed on the aquatic environment. They used the outcomes of a Global Joint Review[5] to set acceptable concentrations for the aquatic environment, including their species sensitivity distribution (SSD) interpretation for acute exposure. The EPA then used the GENEEC2 model (GENeric Estimated Exposure Concentration version 2) to estimate the environmental concentration that would occur. The modelled concentrations were divided by the acceptable concentrations to derive a risk quotient, which is used to identify if the estimated concentration is of concern. The EPA concluded that the active ingredient of Exirel presented less risk than previously thought; that is, there were negligible acute risks for all species and negligible chronic risks for non-threatened species. Further consideration of the conservatism of the models led the EPA to conclude that the risks to threatened species from chronic exposure were negligible also.

4.26 They then explained the confusion on the buffer zones that emerged from the previous assessment. In the current assessment, the EPA concluded no buffer zones were required.

4.27 EPA staff summarised the cultural assessment. There is some general concern over ngā rehu a rererangi (aerial applications). Based on Exirel's hazard classification, it could potentially affect taonga species and ngā wai koiora (the aquatic environment) but the potential impacts on mahinga kai are acceptable. Also, aerial application of Exirel is not likely to compromise significant arthropods and provides ngā hua (benefits) for Māori farmers. The cultural assessment noted the importance of buffer zones to Māori.

4.28 EPA staff presented the benefits of aerial application for Exirel. In hill country in particular, it protects soils and crops from damage compared to tractor movement and reduces risks from tractor rollover. Also, Exirel has a lower hazard and risk profile than alternative products applied aerially. When used in an IPM programme, it allows organophosphate pesticide use to be reduced or eliminated.

4.29 They then presented the prescribed controls based on the hazard classification and the recommended variations under section 77 of the Act. EPA staff highlighted the controls for bees from the Hazardous Property Controls (HPC) Notice (Part 4B) and the additional controls proposed by the EPA under section 77A of the Act which allow ground-based and helicopter application, set nozzle size on boom equipment, and label statements.

4.30 EPA staff concluded the proposed use of Exirel results in negligible risks to human health and the environment, when appropriate controls are in place, and that the potential benefits of using Exirel are considered to be significant and non-negligible. The EPA staff recommended that the Committee approve this application.

4.31 The Committee wondered whether the applicant could write anything on the label referring to controls under section 77A. EPA staff confirmed the applicant is free to expand on the regulatory controls.

4.32 The Committee questioned the assessment on buffer zones and asked if the Australian authorities had done a reassessment of their buffer zones. EPA staff responded that they were

[5] APVMA, USEPA, PMRA, HSE and Anses 2013; Report and Proposed Decision of the UK and France made to the European Commission under the Regulation (EC) no.1107/2009 for first approval of an active substance; OECD Joint Review Project, Section B.9: Ecotoxicology Part B: Summary of data evaluation and risk assessment.

not aware of any reassessment from the Australian authorities, with the differences between the buffer zones set by the two agencies probably due to the difference in the use of Exirel and in the approved application rate in each country.

4.33 The Committee then asked why the benefits of the use of the product were not presented two years ago for the previous application, and wondered what the evidence was for the claimed benefits, apart from the Plant & Food report[6] previously mentioned. EPA staff answered that there was no evidence on benefits presented during the previous hearing, especially the ones concerning the reduced use of organophosphates and the reduced impact on beneficial insects. They confirmed that the main evidence is the Plant & Food report[6]. The applicant confirmed the benefits were not identified clearly in the last application and three new Plant and Food reports had been produced over the last three years.

4.34 The New Zealand Agricultural Aviation Association (NZAAA) questioned the controls on the nozzle size and stated the droplet size is the most important. EPA staff confirmed the intent is to control the droplet size and that the label statement must indicate the droplet should be of medium size.

4.35 Apiculture New Zealand asked if other surfactants have been assessed. EPA staff answered that only Exirel has been reassessed.

4.36 New Zealand Beekeeping Incorporated asked if the controls have been followed for the ground-based use of Exirel. EPA staff responded that other agencies in New Zealand were responsible for the enforcement of controls. They explained further that the EPA had assumed new roles and responsibilities since December 2017 to follow-up with these agencies.

Presentations by submitters

4.37 The NZAAA was the first submitter to present at the hearing. They pointed out that the past 20 years showed a decrease in accident rate in the agricultural aviation sector. During the last eight years, there were 16 helicopter accidents which led to fatalities but only one related to ‘agricultural’ operation - a reconnaissance for a future forest spraying operation. 75% of certified operators are NZAAA members and it is estimated that the agricultural aviation industry adds $2 billion value to the New Zealand economy annually.

4.38 They then presented the Aircare programme, launched in 2011, to establish the best practices possible. 29 NZAAA members are currently Aircare accredited. They focused on the aircraft calibration, which is essential to ensure good coverage and efficacy, a good knowledge of the product released and to be sure the product is only going onto the intended treatment area.

4.39 NZAAA presented an outline of their training and qualification programme which can take from three to five years to complete and 1,000 hours of productive flying time (that is delivering product to the target) under direct supervision. They underlined every flight and mission was recorded and showed pictures of acceptable practice over the years.

4.40 EPA staff asked for clarity on the number of applicators accredited. NZAAA reaffirmed that 29 of the 59 NZAAA members are Aircare accredited.

[6] Horrocks A, Walker M. June 2017. IPM strategy development and demonstration for forage and seed brassicas – year 3 report. A Plant & Food Research report prepared for: The Ministry for Primary Industries Sustainable Farming Fund. Milestone No. 61263-M-0301. Contract No. 31609. Job code: P/443018/01. SPTS No. 14847.

4.41 New Zealand Beekeepers Inc. wanted some clarification around the rules on visibility and if a helicopter could apply these chemicals in the dark. NZAAA replied that they are only allowed to work in daylight.

4.42 Representatives of Ngāi Tahu were not present so Apiculture New Zealand continued with their submission. They began by congratulating the applicant on the proposition on the new label.

4.43 Apiculture New Zealand expressed concerns about bee safety in hill country where bees are placed for manuka honey harvest. They stated that it could be challenging to respect the buffer zones due to the shape of the paddocks and when brassica crops are surrounded with trees, bushes and flowering plants.

4.44 They then stated they are prepared to accept the 50 m buffer zones but were disappointed that there was no more research since the last application in 2016.

4.45 They talked about the surfactant used in the mix tank and expressed their wish to see a label statement with a recommendation on the use of canola oil as a surfactant.

4.46 Apiculture New Zealand finished with a reminder that the goal of Integrated Pest Management (IPM) is to minimise pesticide use and asked the EPA about checking compliance with label requirements. They would like to see no spraying between bud burst and petal fall. They concluded that they accept this application will go through if the controls are adequate to protect the bees.

4.47 The Committee asked what proportion of the estimated 400,000 ha to be sprayed annually will be hill country as in the photos Apiculture New Zealand showed. The applicant said they did not know.

4.48 The Committee then considered the relevance of the surfactant matter, given the proposition is not to apply Exirel during flowering. Apiculture New Zealand expressed their concern that mixing Exirel with a surfactant or a drift control agent could be of greater risk for bees.

4.49 The Committee asked about the rationale behind the 50 m buffer zone. Apiculture New Zealand replied it is a common distance adopted by regional councils and was proposed by FMC. They repeated that they acknowledge this 50 m buffer zone.

4.50 FMC reminded the Committee and submitters that they recommend non-ionic surfactant or wetting agent on the label for use patterns in New Zealand and reiterated that these surfactants or drift control agents are also used for ground-based applications so wondered why it would be a greater risk for aerial applications.

4.51 EPA staff answered a few questions that arose during Apiculture New Zealand's presentation. They noted that the buffer zone controls set under the HSNO Act are a minimum standard and the regional councils can set wider buffer zones. They also clarified the process regarding the setting of controls.

4.52 New Zealand Beekeepers Inc. expressed their concerns about bee safety but congratulated the applicant on the proposed label. They reminded the Committee that they rely on the good will of the applicators in following the label instructions and controls. They questioned the effectiveness of monitoring and enforcement activities when bees are affected. They had not seen any prosecution in years.

Applicant's right of reply

4.53 FMC appreciated everyone's support on the proposed label, and acknowledged the benefits of NZAAA's Aircare programme which will improve aerial applications.

4.54 They acknowledged some points brought up by Apiculture New Zealand, including the general lack of information on surfactants but reminded submitters and the Committee that they recommend non-ionic surfactants. They thanked all of the submitters for the open discussions, and the EPA for the appropriate risk assessment produced and the use of globally recognised methodologies.

4.55 They concluded that there was uniform agreement that, with the controls, the benefits are greater than the risks.

4.56 The hearing was adjourned on 12 December 2018, pending resolution of the point of order raised.

Response to point of order

4.57 In response to the point of order from Apiculture New Zealand[7], a Minute from the Committee Chair[8] instructed the EPA to share the point of order and the letters of support requested by the point of order.

4.58 The EPA shared this information[9] and allowed a further submission period of 10 working days to allow parties to the Hearing to provide comments.

4.59 No further submissions were received.

4.60 The hearing was closed on 14 March 2019.

5 Approval re-issue

5.1 A section 63A modified reassessment of a release approval is subject to sections 77, 77A and 77B of the Act. Therefore, the EPA Notice controls will apply to the modified approvals with transitional periods for some. Approvals subject to a modified reassessment need to be reissued, under clause 4(3) of Schedule 7 of the Act, to ensure that those controls would still apply following the EPA using Schedule 7 for a larger number of substances.

5.2 The approval of Exirel has therefore been reissued on 1 March 2019 prior to the completion of this modified reassessment. From this date, the EPA Notice controls apply, with a transitional period that ends on 30 November 2021 for the following notices:

- Hazardous Substances (Labelling) Notice 2017
- Hazardous Substances (Packaging) Notice 2017
- Hazardous Substances (Safety Data Sheet) Notice 2017.

[7] https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP203558/APP203558-ApicultureNZ-PointOfOrderToDMCchair-Redacted.pdf

[8] https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP203558/APP203558-Minute-05Feb19.pdf

[9] https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP203558/APP203558-Combined-letters-support-Redacted.pdf

6 Consideration

Information available for consideration

6.1 The information available to the Committee for consideration of this application consisted of:

- the application form
- confidential material submitted by the applicant with the application form, including letters of support
- the submissions
- information received from WorkSafe
- previous EPA risk assessments
- updated EPA risk assessment specific to this reassessment
- EPA cultural assessment
- hearing presentations made by the applicant, EPA and submitters.

6.2 After considering all relevant information, the Committee decided that it had sufficient information to make a decision on this application. Further comments on this information can be found below.

Hazardous classifications

6.3 The hazardous properties of Exirel remain unchanged since the original application as no new information was available to inform a review of the hazards. The classification of Exirel is summarised below.

Table 1 Hazard classifications of Exirel

Hazard	Classification
Skin irritancy/corrosivity	6.3A
Contact sensitisation	6.5B
Target organ or systemic toxicity (oral and inhalation)	6.9B
Aquatic ecotoxicity	9.1A
Terrestrial invertebrate ecotoxicity	9.4B

Proposed modification of controls

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

- prescribed controls, that is those triggered by the hazard classifications of Exirel
- variations to the prescribed controls in accordance with section 77 of the Act
- additional controls, proposed in accordance with section 77A of the Act.

Assessment of risks

6.5 The Committee took into account the EPA risk assessment for Exirel, as detailed in the Staff Report. The key points are summarised below.

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

6.6 The Committee considered that the risks during manufacture, packaging, importation, transportation, storage and disposal will remain at a negligible level, given that exposure is unlikely to occur and that the proposed controls and other legislative requirements will sufficiently mitigate the risks associated with these stages of the substance lifecycle. These include the existing Hazardous Substances Notices around packaging, 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 health and safety at work requirements.

Risks during use

6.7 The Committee noted that there is the potential for exposure to humans and the environment to occur during the use phase of the substance and considered the human health and environmental risk assessments provided by the EPA.

Human health effects

6.8 The Committee noted that the EPA did not repeat the work done in the previous risk assessment (APP202774) and considered the comments from Worksafe New Zealand. The Committee determined that the predicted exposures during mixing, loading and application by operators, re-entry workers and for bystanders would be negligible and resulted in risk quotients below the acceptable operator exposure level (AOEL). The Committee noted that the operator exposures would be lower for aerial application.

6.9 The Committee considered that aerial application of Exirel would not pose risks to human health if appropriate controls are in place.

Environmental effects

Risks to soil organisms, non-target plants, sediment-dwelling organisms and birds

6.10 The Committee noted that the EPA did not repeat the work done in the previous risk assessment (APP202774) and considered the risks to soil organisms, non-target plants, sediment-dwelling organisms and birds to be negligible.

Risks to pollinators and non-target arthropods

6.11 The Committee noted that the EPA did not repeat the work done in the previous risk assessment (APP202774) and considered there were potential risks to bees through acute oral exposure for both ground-based and aerial applications; however, the risks to bees through acute contact exposure are considered negligible.

6.12 The Committee noted that semi-field and field studies conducted with cyantraniliprole showed no observed effects on colony strength or brood development, and indicated that pre-flowering application of Exirel does not present a risk to bees. The Committee noted that Exirel is intended to be applied to fodder brassicas during the leaf development stage, and considered that this does not represent a high potential exposure to bees, as these plants will be grazed before reaching flowering stage.

6.13 The Committee considered, as it was discussed during the hearing, that the prescribed controls set by the EPA notices will apply once the approval is reissued (cf. chapter 6 "Approval re-issue"), including the Label statement required for class 9.4 pesticides and plant growth regulators (a transitional period applies if necessary) which specifies:

(1) This clause applies to a class 9.4 pesticide or plant growth regulator, if it is in a form that non-target invertebrate pollinators are likely to be exposed to either during, or after, it is applied to a plant.

(2) The label must include the following statement (or words to this effect)—

"Do not apply substance to plants if—

(i) Bees are foraging; or

(ii) The plants are in flower or part flower, and are likely to be visited by non-target invertebrate pollinators (including bees)"

(3) If the Authority has specified a period for the purposes of clause 58(2)(b)(ii)(B) of the Hazardous Substances (Hazard Property Controls) Notice, the label must include the following additional label statement (or words to this effect)—

"Do not apply the substance to a plant if the plant is likely to flower within x days"

(4) For the purposes of subclause (3), x must be replaced by the number of days specified by the Authority.

6.14 The EPA advised the Committee that sensitivity to Exirel was variable in other non-target arthropods. The Committee noted this and considered that the risks to non-target arthropods would be negligible with the proposed controls. In particular, the additional label statement set under section 77A of the Act which specifies the product label must mention: *"Care should be taken when using this substance in Integrated Pest Management as this substance may affect some beneficial insects."*

Risks to aquatic organisms

6.15 The Committee noted the ecotoxicity values used in the previous risk assessment (APP202774) have been reviewed by the EPA following a Global Joint Review of the active ingredient cyantraniliprole.

6.16 The Committee noted the EPA also used the GENEEC2 model to understand whether there are any concerns about the aquatic environment from the aerial use of Exirel.

6.17 The Committee considered that the chronic and acute risks to all aquatic species are negligible and that there are no elevated risks from the aerial use of Exirel.

Buffer zones

6.18 The Committee noted that the previous assessment in APP202774 proposed a 10 m downwind buffer zone for aerial application of Exirel in order to protect the aquatic environment. The models used in that risk assessment were based on an assessment of the impacts of fixed wing application using the EPA's standard risk assessment approach.

6.19 The Committee noted that the Australian Pesticide and Veterinary Medicine Authority (APVMA) assessed the environmental risks from Exirel applied using fixed wing aircraft for the treatment of cotton at an application rate of 60 g ai/ha, with a minimum of seven days between spraying and a maximum of two applications per crop season. This higher application rate resulted in considerably more cyantraniliprole in the environment than the application rate being considered in this application. Higher burdens on the aquatic environment mean that the APVMA required downwind buffer zones to protect that environment.

6.20 The Committee noted that the EPA's updated aquatic risk assessment used endpoints and assessment factors consistent with those used in the EU assessment of cyantraniliprole. These are based on large numbers of reliable studies, and based on this information, the EPA concluded that the aerial application proposed in this application would pose negligible risk to

the aquatic environment. The Committee noted that the EPA risk assessment considered that a downwind buffer zone is not necessary to ensure protection of the aquatic environment.

6.21 The Committee acknowledged that the submitters from Apiculture New Zealand, New Zealand Beekeeping Incorporated and Ngāi Tahu are concerned about this application and that a 50 m buffer zone would address their concerns.

6.22 The Committee, however, considered that a mandatory buffer zone was not required under the HSNO regime. The applicant is still able to recommend a buffer zone to their users, and regional councils are still able to set more stringent buffer zones under the Resource Management Act.

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

6.23 The Committee did not identify any risks to society, the community and the economy, other than those considered previously. The Committee therefore did not consider this further.

Assessment of benefits

6.24 The Committee noted that the applicant referred to several benefits of Exirel in the application and elaborated on these at the hearing with support from submitters, and that the EPA had analysed those benefits in the Staff Report. These benefits are the:

- protection of soils and crops when aerial application is used compared to tractor movements, especially in hill country
- reduction of risks from tractor rollover in hill country (though the discussions at the hearing concluded there are no relevant robust statistics on the comparative risks of helicopter accidents and tractor rollover)
- lower hazard classification and risk profile of Exirel compared with alternative products applied aerially, including organophosphate-containing substances
- use of Exirel in an integrated pest management (IPM) programme allowing organophosphate pesticide[10] use to be reduced or eliminated
- economic benefits to farmers presented at the hearing by the applicant.

6.25 The Committee considered these arguments and noted that the EPA rated them as low or medium benefits in the Staff Report. The presentations at the hearing from FMC and the NZAAA demonstrated some benefits of the aerial application of Exirel.

6.26 The Committee noted that a Plant & Food report[6] concluded that a 35% reduction in the number of insecticides used under IPM occurred if Exirel was part of IPM for forage brassicas.

6.27 The Committee considered the proposed benefits and assessed them as non-negligible.

Cultural assessment

6.28 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.

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[6] Horrocks A, Walker M. June 2017. IPM strategy development and demonstration for forage and seed brassicas – year 3 report. A Plant & Food Research report prepared for: The Ministry for Primary Industries Sustainable Farming Fund. Milestone No. 61263-M-0301. Contract No. 31609. Job code: P/443018/01. SPTS No. 14847.

[10] Organophosphates are a type of broad-spectrum insecticide. The EPA has reassessed many uses of organophosphates, revoking the approvals of some and adding more restrictive controls to others (for example, see reassessment applications APP201045 and APP202142).

6.29 The Committee acknowledged that the buffer zone welcomed in the cultural assessment was not being imposed as a control.

6.30 The Committee considered that with the controls proposed in place, the impact of aerial application of Exirel on the relationship of Māori to the environment would be negligible. The Committee considered that the application is likely to be consistent with the principles of the Treaty of Waitangi.

New Zealand's international obligations

6.31 The Committee noted there were no international obligations regarding Exirel or its active ingredient, cyantraniliprole.

Amendments to proposed controls by the Committee

6.32 In accordance with section 63A(6)(b) of the Act, the Committee took into account the proposed suite of controls and noted that these aligned with best international practice for the mitigation of risks posed to human health and the environment by hazardous substances.

6.33 The Committee would like to emphasise, as discussed during the hearing, that the prescribed controls set by the EPA Notices will apply once the approval is reissued (see section 5), subject to any transitional periods that apply[11]. These prescribed controls include the Label statement required for class 9.4 pesticides and plant growth regulators, which specify:

(1) This clause applies to a class 9.4 pesticide or plant growth regulator, if it is in a form that non-target invertebrate pollinators are likely to be exposed to either during, or after, it is applied to a plant.

(2) The label must include the following statement (or words to this effect)—

"Do not apply substance to plants if—

(i) Bees are foraging; or

(ii) The plants are in flower or part flower, and are likely to be visited by non-target invertebrate pollinators (including bees)"

(3) If the Authority has specified a period for the purposes of clause 58(2)(b)(ii)(B) of the Hazardous Substances (Hazard Property Controls) Notice, the label must include the following additional label statement (or words to this effect)—

"Do not apply the substance to a plant if the plant is likely to flower within x days"

(4) For the purposes of subclause (3), x must be replaced by the number of days specified by the Authority.

6.34 The Committee considered it was not necessary to set a buffer zone control, as the EPA risk assessment concluded that a buffer zone was not necessary to protect the aquatic environment. The Committee, however, noted that the applicant and the submitters agreed on a buffer zone of 50 m and appreciated the constructive communication between the parties.

6.35 The Committee determined that the controls detailed in Appendix A will apply as soon as this decision is published or at the latest at the end of the transitional period specified in Tables A-1, A-2 and A-3 in Appendix A.

[11] Importers, manufacturers and suppliers may use the new prescribed controls subject to a transitional period at any time before that period ends. They must, however, use the new controls after the transitional period ends.

7 Conclusion and decision

7.1 Pursuant to sections 63A(6) of the Act and section 32 of the Hazardous Substances and New Organisms (Methodology) Order 1998 ("the Methodology"), the Committee considered this application to modify an approval. In doing so, the Committee applied all the relevant sections of the Act and clauses of the Methodology.

7.2 The Committee considered all the effects associated with the substance. They considered that the benefits of aerial application of Exirel outweigh the risks, considered as negligible when the suite of controls listed in Appendix A apply. They, therefore, considered that the positive effects of the aerial application of Exirel outweigh the adverse effects.

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

7.4 Consequently, the Committee determined that the application be approved.

Signed by: **Dr Louise Malone**	**Date: 17 April 2019**
Chair, Decision Making Committee **Environmental Protection Authority**	

Appendix A: Controls applying to Exirel

The controls in Table A 1 are prescribed by the EPA Notices. The controls that have been varied by section 77 of the Act are in Table A-2. The additional controls set under section 77A are in Table A 3.

Table A-1 Prescribed controls

Control code	Legislative instrument	Control description	Date of effect
LAB	EPA Labelling Notice 2017	Requirements for labelling of hazardous substances	Before 30 November 2021
PKG	EPA Packaging Notice 2017	Requirements for packaging of hazardous substances	Before 30 November 2021
SDS	EPA Safety Data Sheet Notice 2017	Requirements for safety data sheets for hazardous substances	Before 30 November 2021
DIS	EPA Disposal Notice 2017	Requirements for disposal of hazardous substances	Immediate
HPC-1	EPA Hazardous Property Controls Notice 2017 Part 1	Hazardous Property Controls	Immediate
HPC-3	EPA Hazardous Property Controls Notice 2017 Part 3	Hazardous Property Controls	Immediate
HPC-4A	EPA Hazardous Property Controls Notice 2017 Part 4A	Hazardous Property Controls	Immediate
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B	Hazardous Property Controls	Immediate
HPC-4C	EPA Hazardous Property Controls Notice 2017 Part 4C	Hazardous Property Controls	Immediate

Table A-2 Controls varied under section 77

Control code	Legislative instrument	Variation	Date of effect
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B – clause 50(1)	The following application restrictions apply: maximum application rate of 15 g_{ai}/ha, maximum of three applications per year, and minimum application interval of seven days.	Immediate

Table A-3 Additional controls under section 77A

Code	Control	Date of effect
Use pattern	A person must only use this substance by ground-based[12] or helicopter-boom methods	Immediate
Use restriction	A person must only spray this substance with nozzles equipped to deliver medium spray quality according to ASABE S572 Standard or the BCPC Guideline	Immediate
Label	The following, or equivalent, statements must be stated on the label, in a manner that satisfies clause 9 of the Hazardous Substances (Labelling) Notice 2017. • This substance must be sprayed with nozzles equipped to deliver medium spray quality according to ASABE S572 Standard[13] or the BCPC Guideline[14]. • Use of this substance must be by ground-based[15] or helicopter-boom methods only. • Care should be taken when using this substance in Integrated Pest Management as this substance may affect some beneficial insects.	Immediate

[12] Ground-based methods of applying pesticides include, but are not limited to, application by ground boom, airblast or knapsack, and exclude aerial application methods

[13] American Society of Agricultural and Biological Engineers; July 2018; Spray Nozzle Classification by Droplet Size; ASAE ANSI/ASAE S572.2; https://elibrary.asabe.org/abstract.asp?aid=49050&t=2&redir=&redirType=

[14] As quoted in NZS 8409:2004, Management of Agrichemicals, ISBN 1-86975-001-2 [Appendix Q]

[15] Ground-based methods of applying pesticides include, but are not limited to, application by ground boom, airblast or knapsack, and do not include aerial application methods

HSW Requirements

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

Code	Regulation	Description
HSW2-1	Reg 2.1 - 2.4	Workplace labelling of hazardous substance containers
HSW2-2	Regs 2.5 -2.10	Signage requirements
HSW2-3	Reg 2.11	Safety data sheets
HSW2-4	Reg 2.12 - 12.14	Packaging
HSW3-1	Reg 3.1	Inventory
HSW3-2	Reg 3.2 - 3.3	Managing risks associated with hazardous substances
HSW4-2	Regs 4.5 - 4.6	Information, instruction, training and supervision
HSW5-2	Regs 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
HSW13-7	Regs 13.13-13.16	Transportation of certain class 6 and 8 substances
HSW13-8	Reg 13.17	Prohibition on use of substance in excess of tolerable exposure limit
HSW13-9	Reg 13.18	Duty of PCBU to ensure prescribed exposure standards for class 6 substances not exceeded
HSW13-14	Reg 13.30 - 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 surface containers

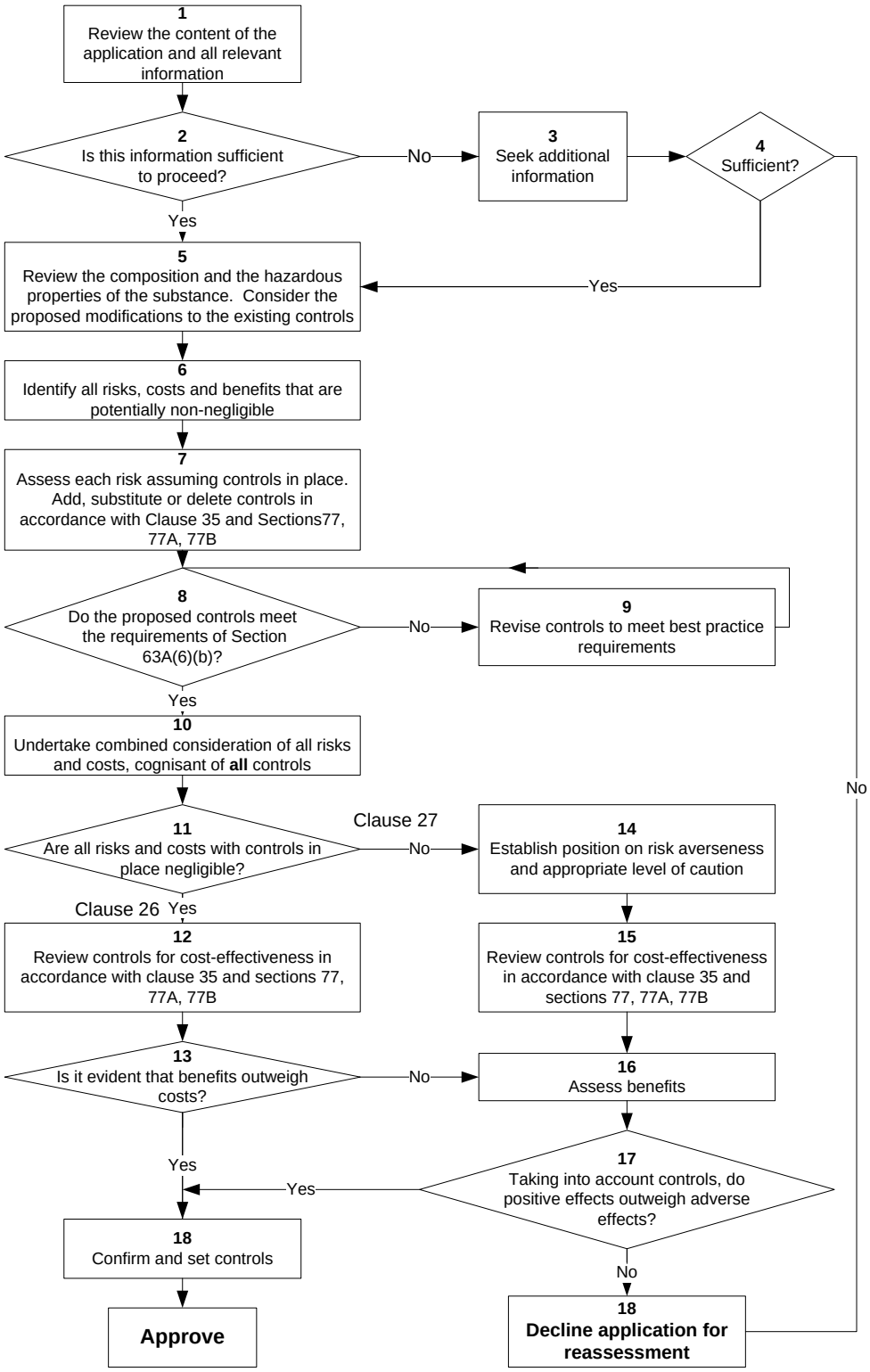
Appendix B: Decision Path

Context

This decision path describes the decision-making process for applications for a modified reassessment for amendments to hazardous substances approvals. These applications are made and determined under section 63 of the HSNO Act.

Decision path for modified reassessment for amendments to hazardous substance approvals: application made and determined under section 63A.

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



Explanatory Notes

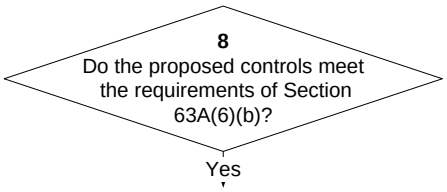
Item 1:	**Review the content of the application and all relevant information** Review the application, the E&R Report, and information received from experts and that provided in submissions (where relevant) in terms of section 28(2) of the Act and clauses 8, 15, 16 and 20 of the Methodology. While section 63A is not mentioned in section 53 (public notification), sections 63A(4) and (5) provide discretion for the HSNO decision maker to consider public notification (cf section 53(2)) and guidance re consultation where an application is not publicly notified.
Item 2:	**Is this information sufficient to proceed?** Review the information and determine whether or not there is sufficient information available to make a decision.
Item 3:	**(if 'no') Seek additional information** If there is not sufficient information then additional information may need to be sought under section 52 or 58 of the Act. If the applicant is not able to provide sufficient information for consideration then the application is not approved. In these circumstances the HSNO decision maker may choose to decline the application, or the application may lapse.
Item 4	**Sufficient?** When additional information has been sought, has this been provided, and is there now sufficient information available to make a decision? If the HSNO decision maker is not satisfied that it has sufficient information for consideration, then the application for reassessment must be declined (see item 18).
Item 5:	**(if 'yes' from item 2 or from item 4) Review the composition and the hazardous properties of the substance, and the proposed modifications to the existing controls** Review the composition of the substance, its hazardous properties, and the existing suite of controls on the substance. The level of detail for this review will depend on the nature of the application for modified reassessment. In most cases a detailed review will not be required. Consider the proposed modifications to the existing controls.
Item 6:	**Identify all risks, costs and benefits that are potentially non-negligible[16]** The modified reassessment process concentrates on a specific aspect of the approval (section 63A(1)(a)). All risks, costs and benefits that are potentially non-negligible need to be identified. However, emphasis should be placed on effects that are expected to change as a result of the proposed changes to controls.

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

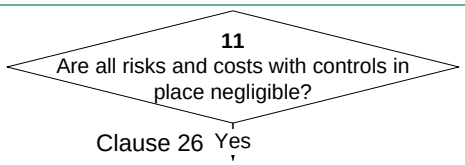
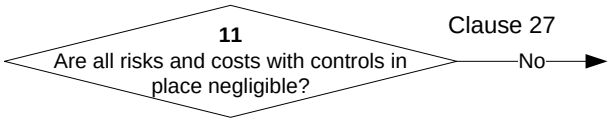
	Costs and benefits are defined in the Methodology as the value of particular effects. However, in most cases these 'values' are not certain and have a likelihood attached to them. Thus costs and risks are generally synonymous and may be addressed together. Examples of costs that cannot be considered as risks are one-off direct financial costs incurred by applicants that cannot be considered as 'sunk' costs (see footnote 1). Where such costs arise they will considered in the same way as risks, but their likelihood of occurrence will be more certain. Identification is a two-step process that scopes the range of possible effects (risks, costs and benefits).	
	Step 1:	Identify all possible risks and costs (adverse effects) and benefits (positive effects) associated with the approval of the substance(s), and based on the range of areas of impact described in clause 9 of the Methodology and sections 5 and 6 of the Act[17]. 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[18], 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.	

[17] 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.

[18] 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.

	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[19]. Where it is clear that residual risks are non-negligible and where appropriate controls are available, add substitute or delete controls in accordance with sections 77 and 77A of the Act to reduce the residual risk to a tolerable level. If the substance has toxic or ecotoxic properties, consider setting exposure limits under section 77B. While clause 35 is relevant here, in terms of considering the costs and benefits of changing the controls, it has more prominence in items 12 and 15. If changes are made to the controls at this stage then the approach to uncertainty and the approach to risk must be revisited.
Item 8:	**Do the proposed controls meet the requirements of Section 63A(6)(b)?** Consider whether the proposed controls meet best international practices and standards for the safe management of hazardous substances. This includes the full suite of proposed controls including existing controls and modified controls.
Item 9:	**(if 'no' from item 8) Revise controls to meet best practice requirements** If the controls do not meet the best international practice criteria, then modify the controls so that they do meet them.
Item 10:	 **(if 'yes' from item 8) Undertake combined consideration of all risks and costs, cognisant of proposed controls** Once the risks and costs have been assessed individually consider all risks and costs together as a 'basket' of risks/costs. If it is feasible and/or appropriate, this may involve combining groups of risks and costs as for Clause 34 of the Methodology. The purpose of this step is to consider synergistic effects and determine whether these may change the level of individual risks.
Item 11:	**Are all risks and costs with controls in place negligible?** Looking at individual risks in the context of the 'basket' of risks, consider whether any of the residual risks (costs) are negligible.

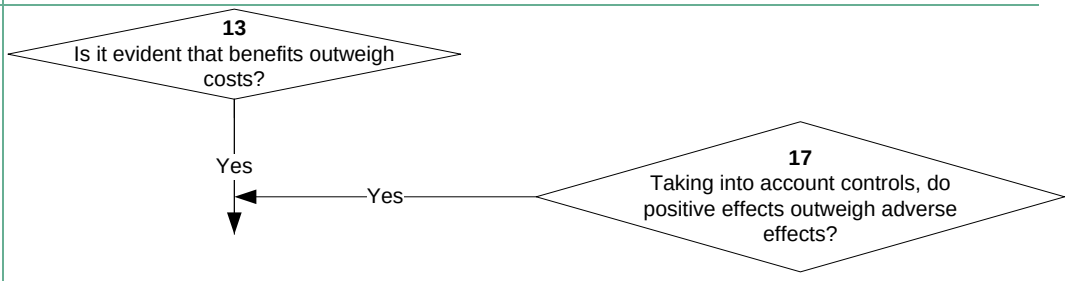
[19] http://www.epa.govt.nz/Publications/Approach-to-Risk.pdf

Item 12:	 **(if 'yes' from item 11) Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B** Where all risks are negligible the decision must be made under clause 26 of the Methodology. Consider the cost-effectiveness of the proposed individual controls and exposure limits. Where relevant and appropriate, add, substitute or delete controls whilst taking into account the view of the applicant, and the cost-effectiveness of the full package of controls.
Item 13:	**Is it evident that benefits outweigh costs?** Risks have already been determined to be negligible (item 9). In the unusual circumstance where there are non-negligible costs that are not associated with risks they have been assessed in item 7. Costs are made up of two components: internal costs or those that accrue to the applicant, and external costs or those that accrue to the wider community. Consider whether there are any non-negligible external costs that are not associated with risks. If there are no external non-negligible costs then external benefits outweigh external costs. The fact that the application has been submitted is deemed to demonstrate existence of internal or private net benefit, and therefore total benefits outweigh total costs[20]. As indicated above, where risks are deemed to be negligible, and the only identifiable costs resulting from approving an application are shown to accrue to the applicant, then a cost-benefit analysis will not be required. The act of an application being lodged will be deemed by the HSNO decision maker to indicate that the applicant believes the benefits to be greater than the costs. However, if this is not the case and there are external non-negligible costs then all benefits need to be assessed (via item 16).
Item 14:	 **(if 'no' from item 10) Establish HSNO decision maker's position on risk averseness and appropriate level of caution** Although 'risk averseness' (approach to risk, clause 33) is considered as a part of the assessment of individual risks, it is good practice to consolidate the view on this if several risks

[20]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'

	are non-negligible. This consolidation also applies to the consideration of the approach to uncertainty (section 7).
Item 15:	**Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B** This constitutes a decision made under clause 27 of the Methodology (taken in sequence from items 10, 13, 14 and 15). Consider (a) whether any of the non-negligible risks can be reduced by varying the controls in accordance with section 77 and 77A of the Act, and (b) the cost-effectiveness of the controls. Where relevant and appropriate, add, substitute or delete controls whilst taking into account the view of the applicant, and making sure that the benefits of doing so outweigh the costs. As for item 6, If the substance has toxic or ecotoxic properties, consider exposure limits under section 77B.
Item 16:	**(if 'no' from item 13, or in sequence from item 15) Assess benefits** Assess benefits or positive effects in terms of clause 13 of the Methodology. Since benefits are not certain, they are assessed in the same way as risks. Thus the assessment involves estimating the magnitude of the effect if it should occur and the likelihood of its occurring. This assessment also includes consideration of the HSNO decision maker's approach to uncertainty or how cautious the HSNO decision maker will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the positive effect. An understanding of the distributional implications of a proposal is an important part of any consideration of costs and benefits, and the distribution of benefits should be considered in the same way as for the distribution of risks and costs. The HSNO decision maker will in particular look to identify those situations where the beneficiaries of an application are different from those who bear the costs[21]. This is important not only for reasons related to fairness but also in forming a view of just how robust any claim of an overall net benefit might be. It is much more difficult to sustain a claim of an overall net benefit if those who enjoy the benefits are different to those who will bear the costs. Thus where benefits accrue to one area or sector and risks and costs are borne by another area or sector then the HSNO decision maker may choose to be more risk averse and to place a higher weight on the risks and costs. As for risks and costs the assessment is carried out with the default controls in place.
Item 17:	**Taking into account controls, do positive effects outweigh adverse effects?** In weighing up positive and adverse effects, consider clause 34 of the Methodology. Where possible combine groups of risks, costs and benefits or use other techniques such as dominant risks and ranking of risks. The weighing up process takes into account controls proposed in items 5, 7 (9), 12 and/or 15. Where this item is taken in sequence from items 14, 15 and 16 (i.e. risks are not negligible) it constitutes a decision made under clause 27 of the Methodology. Where this item is taken in sequence from items 11, 12 and 13 (i.e. risks are negligible, and there are external or public costs) it constitutes a decision made under clause 26 of the Methodology.

[21] Clause 13 of the Methodology

Item 18:	**(if 'no' from item 4 or item 17) Decline application for reassessment** (from item 4) The Act is silent on the situation if there is insufficient information to consider the application. However, sections 55-61 (section 63A(3)) are deemed to hold, therefore the HSNO decision maker concludes that the application for reassessment may be declined if there is insufficient information. (from item 17) The HSNO decision maker may decline the application under section 63A(6) after taking into account the effects of the substance and best international practices and standards. Section 63A(2)(b) notes that this modified reassessment process cannot result in an approval to import or manufacture the substance being revoked. Therefore, if the process results in a 'decline' decision, then the result is that the modified reassessment of the substance is not approved, and the existing controls remain in force.
Item 19:	 **(if 'yes' from items 13 or 17) Confirm and set controls** Controls have been considered at the earlier stages of the process (items 5, 7 (9), 12 and/or 15). The final step in the decision-making process brings together all the proposed controls, and reviews them for overlaps, gaps and inconsistencies. Once these have been resolved the controls are confirmed.