Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

1 September 2016

1. Summary

Substance	Exirel ®
Application code	APP202774
Application type	To modify an existing approval for a hazardous substance under Section 63A of the Hazardous Substances and New Organisms Act 1996 (“the Act”)
Applicant	DuPont (New Zealand) Limited
Purpose of the application	To reassess DuPont Exirel® Insecticide, a suspo-emulsion containing 100 g/L cyantraniliprole as the active ingredient, for aerial application.
Date application received	23 March 2016
Hearing date	27 July 2016
Consideration date	27 July 2016
Considered by	Dr John Taylor– Chair Dr Kerry Laing Dr Sharon Adamson
Decision	Declined
Hazard classifications	6.3A, 6.5B, 6.9B, 9.1A, 9.4B

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2. Executive summary

2.1. Exirel® is a suspo-emulsion that contains 100 g/L cyantraniliprole as the active ingredient. It was approved under the Hazardous Substances and New Organisms (HSNO) Act (the Act) on 28 June 2013.

2.2. The application to modify the existing approval for Exirel® was made by DuPont New Zealand Limited and was publically notified in accordance with section 53 of the Act.

2.3. During the submission period, four submissions were received on the application; from the Apiculture New Zealand Technical Focus Group ('ApiNZ'), Te Rūnanga o Ngāi Tahu (Ngāi Tahu), Ngāpuhi HSNO Komiti ('Ngapuhi'), and The Honeybee Society Inc ('HBS'). Of these submitters, ApiNZ did not indicate whether they supported or opposed the application, Ngāi Tahu and Ngāpuhi opposed the application, and HBS supported the approval of the application.

2.4. ApiNZ and Ngāi Tahu requested to speak at a hearing and on 27 July 2016 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 Don MacLeod and Barry Foster of ApiNZ, and Oliver Sutherland and Gerry Te Kapa Coates of Ngāi Tahu.

2.5. After considering all relevant information available at the time of the hearing, the Committee decided that it had sufficient information with which to make a decision on this application.

2.6. With the suite of controls presented in the Staff Report, the Committee assessed the risks posed by aerial application of Exirel® and determined that they would be non-negligible. The Committee assessed the level of benefits associated with aerial application of Exirel® and determined that they would be negligible. In accordance with section 63A(6) of the Act, the Committee decided to decline the application to modify the existing approval for Exirel®.

2.7. Grounds for this reassessment were established under section 62(2)(c) of the Act by the EPA in its decision dated 19 November 2015. In its decision, the EPA determined that grounds exist for reassessing Exirel® based on the proposed change of use to include aerial application methods. As such, this met the criterion that information showing a significant change of use, or a significant change in the quantity manufactured, imported, or developed had become available.

2.8. In reaching its conclusion, the Committee has applied the precautionary approach prescribed by section 7 of HSNO Act. This section states that there is a requirement to take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.

3. Identification and intended use

3.1. Exirel® is currently approved for use at 50 g a.i./ha ground based application, with a maximum of three applications per year with a minimum interval of seven days. The applicant has requested aerial application at an application rate of 15 g a.i/ha, three times a year with a minimal interval of 14 days.

3.2. Exirel® is intended for application on brassicas (turnips, swede forage, rape and kale). It contains 100 g/L cyantraniliprole as the active ingredient.

3.3. Exirel® was approved under the Act on 28 June 2013 (HSR100857). That approval restricted the application of Exirel® to ground-based methods only.

4. Application process

Formal receipt and notification

4.1. The application was formally received by the EPA on 23 March 2016.

4.2. The Minister for the Environment was advised of the application in writing on 8 April 2016, in accordance with section 53(4) of the Act. The Ministry for the Environment, WorkSafe New Zealand, the Ministry of Health, the Department of Conservation, and the Agricultural Compounds and Veterinary Medicines (‘ACVM’) group of the Ministry for Primary Industries were advised of the application and notified of the submission period. No comments or submissions on the application were received from these parties.

4.3. The application was publicly notified and opened for submissions on 8 April 2016. The submission period closed on 23 May 2016.

Submissions received

4.4. Four submissions were received in response to public notification of the application. All submissions expressed concern about the potential impact on the environment. Submitters generally noted:

- The potential use of surfactants and enhanced toxicity and ecotoxicity effects
- Concern with the practicalities of proposed controls and their enforceability, particularly around the protection of bees
- Concern with the ambiguity of wording present on the product label
- Breach of principle in relation to ‘active protection’ in the Treaty of Waitangi
- Concern with risks to the aquatic environment.

4.5. The Committee took account of these submissions in making its decision.

5. Requirements of section 63A of the Act

5.1. Under section 63A(1) of the Act, a modified reassessment may be carried out where the reassessment will involve only a specific aspect of an approval and the proposed amendment is not a minor or technical amendment to which section 67A of the Act applies.

5.2. The Committee considered that-

- a reassessment of the substance under section 63 of the Act is not appropriate because the reassessment involves only a specific aspect of the approval, i.e. aerial application methods as opposed to ground-based application methods.
- the amendment is not "minor in effect", or a minor or technical amendment.

5.3. Under section 63A(6) of the Act, the EPA may approve or decline an application for reassessment under section 63A of the Act after taking into account:

- all the effects associated with the reassessment; and
- the best international practices and standards for the safe management of hazardous substances.

6. The Evaluation and Review Report (Staff Report) and additional information

6.1. The Staff Report is the staff's review of the application and available data regarding the substance and provides information to assist the Committee's decision-making. The staff conducted quantitative human health and environmental risk assessments to consider additional risks posed by aerial application at the proposed rate. These assessments considered the exposure and subsequent effects on people and the environment throughout the life cycle of the substance.

6.2. Based on all the available information, the staff assessed the potential risks that aerial application of the substance may pose to the environment, human health, the relationship of Māori to the environment, society, and the economy.

6.3. The staff identified a suite of default controls based on the hazard classifications of Exirel®. They also considered variations to these controls, and the addition of extra controls, in accordance with section 77 and section 77A of the Act.

6.4. The Staff Report concluded that with the default controls, the proposed variations to these controls, and the addition of extra controls, the risk to human health and the environment would be managed. The staff recommended to the Committee that with the proposed controls in place, the overall level of benefit provided by the modification of the existing approval of Exirel® to include aerial application would outweigh the overall risk.

7. The Hearing and Consideration Process

Hearing

7.1. On 27 July 2016, a hearing was held at the Willeston Conference Centre in Wellington. Presentations were given by the applicant, the EPA staff and submitters.

Applicant's presentation

7.2. The Exirel® application was represented by Greg Mitchell and Mark Christie of DuPont New Zealand.

7.3. Mr Mitchell began by outlining the purpose of the hearing and the grounds for a reassessment of Exirel®. He noted the reduction in the proposed application rates from 50 g/ha of active ingredient to 15 g/ha of active ingredient for aerial application and an increase in the minimum time interval between applications from seven to fourteen days. He also noted that although the set maximum number of application is three per year, in reality it would be unlikely that growers would use the maximum number of applications.

7.4. Mr Mitchell spoke about the benefits of aerial application using helicopters over fixed-wing aircraft. He noted the limited number of fixed-wing aircraft available to growers for aerial application. He also noted the topography and layout of larger areas which have paddocks interspersed within grazing pastures. Smaller areas do not always have long runs over flat land, indicating that aerial application by fixed-wing aircraft would be less effective than by helicopters, which are able to move easily between areas.

7.5. Mr Mitchell spoke about the risks to human health. He noted that there is "*no additional risk from manufacturing, packaging, importation, transport and storage"* and that the risks remain unchanged from the original application.

7.6. Mr Mitchell noted that the risk from exposure was deemed acceptable at the higher application rate, and that the new reduced rate wouldn't trigger any new risk than has already been assessed. He also noted the requirement for users to have an Approved Handler certificate when mixing, loading and applying Exirel®. He noted this control would ensure users have sufficient knowledge, competence and experience to handle Exirel® safely.

7.7. Mr Mitchell noted the potential risk to bystanders via chemical spray drift is higher due to the aerial application method. However, he noted that diluted spray does not pose a significant exposure risk during unintentional contact and that repeated exposure is mitigated by the restrictions of the application rate, number of applications and spray interval.

7.8. Mr Mitchell discussed the risk to the environment while noting the main change in risk profile is from exposure during use. He noted that risks arising from the change in application method to soil organisms, non-target plants and terrestrial vertebrates remain unchanged and that the current controls mitigate the risks to an acceptable level.

7.9. Mr Mitchell did however note the increased risk to aquatic organisms due to aerial application. He noted that DuPont proposed a 100 metre downwind buffer zone when applied aerially and 5 metres with ground-based application, consistent with the Australian Pesticides and Veterinary Medicines Authority (APVMA) requirements for the application of Exirel® by helicopter.

7.10. Mr Mitchell discussed the risk to aquatic environments from run-off. He noted that irrespective of the application method there is limited risk from run-off to aquatic invertebrates. In addition to this, DuPont also proposed a label statement to inform users not to apply Exirel® if rainfall is expected within two hours of application or if heavy rainfall is likely to generate run-off within 48 hours of application. Mr Mitchell noted that if these controls were followed then risk from run-off would be acceptable.

7.11. The Committee asked for clarification regarding the rain-fastness of the product, especially between the 2 and 48 hour withholding periods. Mr Mitchell responded that significant quantities of the product would be taken into the plant in the first two hours and after that it was more related to ground runoff.

7.12. The application noted the current controls applied to Exirel® to mitigate the risks to honeybees and proposed an additional label statement to ensure "*spray drift is avoided in flowering off-crop habitats*". Mr Mitchell considered these controls would help to mitigate risks during aerial application.

7.13. Mr Mitchell presented a proposed additional label wording, which indicated Exirel® as an effective tool in Integrated Pest Management ('IPM'). He noted that Exirel® would help conserve some parasites and predators, for example, predatory mites. Mr Mitchell explained that DuPont has undertaken trials on Exirel® to demonstrate its effectiveness, irrespective of application method, against pests such as the cabbage white butterfly, diamondback moth, soybean looper, European leaf miner and grey cabbage aphid. He also noted that this information has been submitted to ACVM.

7.14. Barry Foster (ApiNZ) asked for clarification regarding peak pest numbers occurring in January and February. He queried the recommendation that Exirel® be applied one month before flowering. The applicant responded that it wouldn't be time related but that application would be dependent on pest numbers.

7.15. The Committee considered the time period during which Exirel® may be applied in relation to planting brassica crops. Mr Christie responded that the application time for Exirel® would be at the height of pest presence, usually February or March if crops are planted in October or November, depending on environmental factors. He also noted that DuPont is currently conducting a multi-year study to clarify the effects of Exirel® on beneficial insects or managed pest populations. He noted that in the hotter months there is usually a spike in egg numbers and this would be the time to apply Exirel® without affecting the predator populations that are building up. He also highlighted the benefit of aerial spraying during pest outbreaks and the potential for shorter reaction times.

7.16. Mr Mitchell discussed the potential costs of aerial application, while noting that the cost is "negative" for aerial application versus ground based application. He also noted that the cost would restrict the amount of aerial application. He explained that mature crops would require larger volumes of water in

order to receive full coverage. He also presented the benefits of aerial application versus ground-based application; namely the improved safety to farm workers and a reduction in soil compaction. Mr Mitchell noted that there are risks to farm workers using ground-based application rigs on difficult terrain, especially when the ground is wet. He noted that application often occurs in summer months and in places like Southland there is concern with bogging during wet conditions.

7.17. Gerry Coates (Ngāi Tahu) asked for clarification regarding fixed-wing aircraft versus helicopters in relation to aerial application and if the application was restricted to one mode. The applicant replied that all information presented supported the use of helicopters and suggested willingness to restrict aerial application to helicopter; however he noted that the application submitted to the EPA did mention aerial application in broad terms. He noted that the advice received from industry related to the need for aerial application by helicopter.

7.18. Mr Coates questioned the Committee as to whether it would be possible to restrict the application to helicopters only. The Committee asked for clarification from EPA staff as to whether they were aware of any restrictions placed on the type of aerial application. The staff noted they were not aware of a precedent for setting such a restriction to either helicopter or fixed-wing based application methods, however, as with all the controls set for approving hazardous substances the criteria is that they address a specific risk, so in that situation there would be a need to identify that fixed wing aircraft will pose a different risk to that posed by helicopters to be able to set that restriction. The EPA staff had therefore undertaken their risk assessment to account for fixed-wing aircraft in accordance with the broad terms suggested in the application.

7.19. The Committee noted that they are required to consider the information presented in the application when making their decision and had therefore considered the risks from the use of both fixed-wing aircraft and helicopters.

7.20. The Committee considered the issue of safety and soil compaction. The Committee noted that the applicant has stated that Exirel® would be sprayed during the driest time of year, which should be ideal ground conditions. Mr Christie responded that of the ~400,000 hectares of brassicas grown in New Zealand, a large proportion of are grown in Otago/Southland, and that ‘dry’ is a relative term. He also noted that there can be very wet and boggy conditions in the height of summer, especially in western Southland and Otago. He said that a key determinant in choosing an application method is the height of the crop and whether you can get ground-based equipment over the crop. Kale crops are about waist height at time of spraying and this is too high for some ground-based applicators.

7.21. The Committee considered whether there was evidence to suggest high rates of “rollover” during ground-based pesticide application and found little available evidence to substantiate this.

7.22. Mr Mitchell noted the accuracy of aerial application when applied by helicopter, noting the ability to use GPS for tracking and applying agrichemicals. He also noted the use of technology such as “*TracMap”*, which can be used for proof of placement. He noted the use of half boom techniques and nozzle technology, which has helped to reduce drift and overspray.

7.23. Mr Mitchell ended by acknowledging that the risks to Māori are an important aspect to consider and that DuPont appreciated the input from Ngāi Tahu.

7.24. Don MacLeod (ApiNZ) asked for clarification regarding the use of surfactants and what the insect control effects are like with and without surfactants. The applicant responded that the original trials were done with non-ionic surfactants but he was unsure as to the control effects. However, he considered that the studies show that there is no additional toxicity with or without a surfactant.

7.25. Don MacLeod questioned whether the effect on bees was measured with a range of surfactants that would likely be used with Exirel®. The applicant responded that his understanding was that studies have been done with Exirel® with and without codacide oil as a surfactant and the results have shown that there wasn't a difference in toxicity to bees.

7.26. Dr Oliver Sutherland (Ngāi Tahu) questioned whether there was any data on whether the proposed controls would safeguard native bees or other native pollinators. Mr Mitchell responded that the controls were for honeybees and that no studies were available for native bees; however, he noted the proposed buffer zones would mitigate risks of the substance being deposited onto off-crop habitats. The EPA staff clarified that currently the buffer zones were proposed to protect against risk to water bodies and that off-crop habitats were not included in their risk assessment model.

7.27. The EPA staff noted the potential risks to bees through dietary exposure. However, data indicated that pre-flowering application of Exirel® did not present a risk to bees. The staff proposed additional wording to be supplied on labels ensuring the substance is not sprayed on flowering crops or off-crop habitats.

7.28. The Committee clarified whether the proposed control statement on the label is appropriate to protect off-crop flowering habitats or whether a buffer zone would be a more appropriate tool. Dr Ramarosandratana replied that there is potential to set buffer zones to protect off-crop flowering habitats.

7.29. Barry Foster asked for clarification around whether applying Exirel® in forage brassicas in pre-flower stage means that there is potential for flowering weeds to be present. Dr Ramarosandratana noted that the proposed label statement would advise growers not to spray when flowering weeds are present and to avoid spray drift to off-crop habitats.

7.30. The Committee considered the proposed statement regarding "*DO NOT spray during bee flight"* could be made more specific as users may not be aware of when bees fly in a specific locality. The staff noted the ambiguity around the label statement.

7.31. The Committee considered that the proposed controls would protect both native and non-native pollinators but recognised a gap in the available information on the types of environments being protected in this modified reassessment.

EPA staff presentation

7.32. Dr Anna Ramarosandratana represented the EPA staff and addressed the hearing, providing an overview of the Staff Report and the results of the modified reassessment for Exirel®. She noted that Exirel® is not a new product and has been approved for use and is available in New Zealand.

7.33. Dr Ramarosandratana explained that in 2012 the initial application for Exirel® from DuPont was processed as a Category C application because at that time cyantraniliprole was a new active ingredient in New Zealand. She noted a full risk assessment was conducted on the active ingredient, and that in 2013, Exirel® was approved for use in New Zealand.

7.34. The staff considered that the risks to human health are below the Acceptable Operator Exposure Level (AOEL). The staff noted that the hazard classifications of Exirel® trigger default controls including a requirement for Personal Protective Equipment (PPE) when handling the substance. The staff considered the PPE requirements and the results of the assessment and determined that the risks to human health were negligible for both ground-based and aerial application methods.

7.35. Dr Ramarosandratana noted the risks to the environment and the potential for Exirel® ® to cause adverse effects to threatened species. As a result a more conservative approach was taken using uncertainty factors in the assessment that take into account the potential impact on threatened species' populations.

7.36. The EPA staff noted that there are risks to threatened and non-threatened aquatic invertebrates and to sediment dwelling organisms from both application methods and discussed the proposed controls to mitigate the risks to the aquatic environment; namely through the use of buffer zones which would reduce the amount of spray drift onto water bodies to a safe level. Dr Ramarosandratana discussed the spray drift modelling that was used to determine the size of buffer zone. She noted a medium to fine spray droplet size was used as a parameter in the model, and that staff considered buffer zones of 10 metres for aerial application and 2 metres for ground-based application to be appropriate.

7.37. The EPA staff compared the results from Australian modelling and the EPA modelling and considered the apparent inconsistency between the two, noting that the EPA modelling resulted in smaller buffer zones due to the parameters used. The staff noted that:

- the Australian application rate is 60 g a.i/ha, which is four times higher than proposed in the application
- there is a difference in boom height because of the different crop height (cotton and canola crops versus brassicas)
- Australia has a more conservative water body size, both in water depth and width
- the EPA model considers sorption to sediment, which the Australian model does not.

7.38. The EPA staff also noted they were unable to identify the eco-toxicity endpoint used in the Australian model which would influence the outcome.

7.39. EPA staff recommended that, with all the proposed controls in place, the application be approved.

7.40. The Committee sought clarification about the parameters that were used in the spray drift modelling. The staff responded that the model used standard parameters, which consist of worst case rates and scenarios that assume the highest wind speed at which an aircraft would be permitted to fly.

7.41. Don MacLeod questioned whether hilly terrain was factored into model for spray drift and staff confirmed that the modelling undertaken had not accounted for hilly topography.

7.42. Dr Sutherland asked for clarification on whether fixed-wing aircraft or helicopters were used to determine the buffer zone. The staff confirmed that the model was based on fixed-wing aircraft and noted that helicopters presented lower risks.

7.43. Gerry Coates asked for clarification around the size of buffer zones noting the difference between the EPA model and the Australian model. The Committee noted the difference in parameters used, including the rate and use pattern, and considered it appropriate for the EPA to conduct their own assessment based on New Zealand parameters to determine what an appropriate buffer zone is.

Presentations by submitters

7.44. Mr Foster presented photographs of fodder brassicas in typical hilly country. He noted that there are pockets within the paddocks, which are unable to be cultivated due to gullies and steep slopes. He discussed the likelihood of clover, weeds, trees and shrubs that would provide refuges for bees to forage when in flower. He noted the difficulty in aerial application in relation to adhering to the proposed buffer zones.

7.45. Mr MacLeod discussed the limitations for spray drift modelling when using AGDISP and AGDRIFT. He noted *"the current models assume a flat earth and steady-state ambient conditions".* He explained this was major limitation to the current algorithms and that they should not be used in hilly country applications.

7.46. Mr MacLeod identified the label statements from the original application, which he believed were not practical to implement and in some instances were ambiguous. He noted the "*label instructions are contradictory and invalidate good agricultural practice which the EPA is striving for*".

7.47. Mr Coates noted that Ngāi Tahu opposed the application for reassessment. However, he commented that "*we do appreciate DuPont's effort for communicating with Ngāi Tahu*". He noted that Ngāi Tahu do not find any compelling reasons for applying Exirel® by air and cited a lack of evidence showing brassica crops growing on hilly country.

7.48. Mr Coates concluded by stating Ngāi Tahu's support for the concerns raised by Ngāpuhi about the potential effects of Exirel® on New Zealand native species, especially pollinators. He also noted that a persuasive case for benefits to Māori as Treaty partners has not been made in this reassessment.

8. Consideration of effects

8.1. The following information was considered by the Committee:

- The application and its confidential appendices
- The submissions
- The EPA Staff Report
- Information presented at the hearing by the applicant, the submitters, and the EPA staff.

8.2. Further comments on this information can be found in the sections following.

Hazard classifications

8.3. The Committee adopted the hazard classifications for Exirel® as recommended by the staff, based on the information provided by the applicant and on other available information as documented in the Staff Report (Table 1). This information included study data, as well as mixture rules calculations.

Table 1: Hazard classification of Exirel®

Hazardous property	Classification
Skin irritant	6.3A
Contact sensitisation	6.5B
Target organ or system toxicity	6.9B (oral, inhalation)
Aquatic ecotoxicity	9.1A
Terrestrial invertebrate ecotoxicity	9.4B

Identification of controls

8.4. The suite of controls proposed by the staff, and considered by the Committee was detailed in full in Appendix C of the Staff Report. The control suite included:

- default controls i.e. those triggered by the aquatic ecotoxicity hazard classification of Exirel®
- deletions and variations to the default controls in accordance with sections 77 and 77A of the Act
- additional controls, proposed in accordance with section 77A of the Act.

Assessment of benefits

8.5. The applicant referred to several benefits of the substance in the application and elaborated on these at the hearing. The staff also provided some information to support these claims. The applicant proposed specific benefits that could arise from aerial application of Exirel®; primarily, the applicant noted that this would permit application of Exirel® on uneven terrain or during wet conditions. They explained that this is expected to lead to flow-on benefits including:

- Reduced health risks to vehicle operators who currently drive spray rigs on difficult or dangerous terrain and thereby have a risk of ‘rollover’.

- Preserved soil quality, as the use of heavy equipment on wet soil or pugged pasture can decrease soil quality and have negative impacts on yield and land productivity.
- An ongoing ability to apply Exirel® to crops, minimising the development of increased pest pressure and retaining the ability to adhere to recommended application frequencies.

8.6. The Committee considered the argument for the improved safety of farm workers. They noted that while the conceptual basis of the argument is plausible, no evidence was presented to demonstrate whether ground based application presents a real risk to the health and safety of farm workers. No historical record of accidents was presented. The Committee also considered the benefit to farmers given that ~30% of fodder brassica crops are sprayed in New Zealand and that there are further limitations on the extent of aerial spraying due to the higher cost. Based on the evidence provided, the Committee considered that this benefit would be negligible.

8.7. The Committee considered the issue of soil compaction as outlined by the applicant. The Committee noted that it had not received any submissions supporting this, nor was there specific information to support this benefit. The Committee noted that other elements of soil compaction, such as livestock walking across the crop field, had not been considered in the application, but these elements were mentioned at the hearing by Don MacLeod. The Committee noted that this could have an equal or more significant effect than spraying equipment. The Committee therefore considered this benefit would be negligible.

8.8. The Committee considered that the applicant had not mentioned any potential for increased area that is able to be sprayed, and had not presented data showing increased crop yield. This negated the EPA staff's assessment that a positive effect of aerial application might be increased crop yield. The Committee was unable to determine whether this effect was significant based on the information available to it and therefore considered this benefit would be negligible.

8.9. The Committee considered the proposed benefit of aerial application facilitating a rapid response to control an outbreak of pests, but considered that there is insufficient supporting data about the economic impacts of pest pressure and no comparison with the existing ability to conduct ground applications in such situations. The Committee therefore considered this benefit would be negligible.

8.10. In summary the Committee considered the proposed benefits but found no evidence to indicate that the benefits would occur over and above the current benefits derived from using Exirel® via ground based application. The Committee therefore assessed the benefits as negligible.

Assessment of risks

Risks during manufacture, packaging and importation

8.11. The risks during manufacture, packaging and importation remain the same as with the current approval and have not been considered in depth as part of this decision.

Risks during transport and storage

8.12. The Committee considered that people and the environment would only be exposed to the substance during transport and storage in isolated incidents where a spill occurs. Once in New Zealand, HSNO controls (e.g. labels, safety data sheets and packaging) and adherence to the Land Transport Rule 45001, Civil Aviation Act 1990 and Maritime Transport Act 1994 would apply.

8.13. The Committee considered that adherence to the HSNO controls (such as labelling, SDS, packaging emergency management and secondary containment) during transportation and storage would ensure that the level of risk to the environment from Exirel® would be negligible.

Risks during use

Human health effects

8.14. The Committee noted that the staff's quantitative human health risk assessment for ground-based application of Exirel®, detailed in the Staff Report, 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 exposures would be lower for aerial application due to the lower application rate.

8.15. The Committee considered that aerial application of Exirel® would not pose risks to human health.

Aquatic organism effects

8.16. The Committee reviewed the evidence provided to it with regard to aquatic organisms. The Committee determined that aerial application, without additional controls, would result in increased risks to aquatic invertebrates.

8.17. The Committee considered downwind buffer zones that could be used to mitigate the risks to aquatic organisms. The Committee concluded that a sufficiently large buffer zone would reduce the risks to aquatic organisms to a negligible level but noted that there is considerable uncertainty regarding what this appropriate buffer zone should be given the variety of topography where Exirel® may be applied aerially.

8.18. The Committee recognised that the while the applicant requested that the buffer zone for aerial use of Exirel® be set at 100 metres, consistent with a risk assessment carried out by Australian regulators, the adoption of this distance in New Zealand might reasonably be expected to exclude a significant portion of forage brassica crops growing in smaller fields in hilly topography. This restriction is likely to reduce the potential benefits of Exirel® in New Zealand. The Committee considered that the fact that the model does not take into account hilly terrain results in uncertainty in the buffer zone calculated for aerial application in such circumstances.

8.19. The Committee noted that where any scientific or technical uncertainty or dispute is not resolved during its consideration of the application, "*the Authority must take into account the need for caution in managing the adverse effects of the substance*".

Terrestrial invertebrate effects

8.20. The Committee noted the EPA staff advice that Exirel® ® posed a possible risk to bees through acute oral exposure. The Committee noted that this risk was present for both ground and aerial based application of Exirel®.

8.21. The Committee considered 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 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.

8.22. The Committee noted the staff's recommendation for the following label statements regarding the safety of honeybees:

- *DO NOT apply this insecticide to flowering crops.*
- *Take all reasonable steps to ensure that flowering weeds are removed from the application area before spraying Exirel®,*
- *DO NOT apply during bee flight*

8.23. The staff advised the Committee that sensitivity to Exirel® was variable in other non-target arthropods. The Committee noted this and considered that with the proposed controls, the risks to non-target arthropods would be negligible.

Assessment of risks to other organisms

8.24. The Committee noted the EPA staff risk assessment for soil organisms and birds. Based on the information provided the Committee considered the risks to be negligible.

Risks during disposal

8.25. The risks during disposal remain the same as with the current approval and have not been considered in depth as part of this decision.

Relationship of Māori to the environment

8.26. The Committee noted that the staff assessed the potential effects on the relationship of Māori to the environment in accordance with sections 6(d) and 8 of the Act. This included an assessment of the potential impacts of Exirel® on kaitiakitanga and the Treaty of Waitangi.

8.27. Ngāi Tahu noted that the amount of data made available to the public was extremely limited and that this made it impossible to evaluate the potential for risk. They also considered that the approval of an application for a hazardous substance, where uncertainty exists regarding the potential for adverse effects on taonga species and traditional Māori values and practices, may be viewed as being inconsistent with the principle of active protection in the Treaty of Waitangi.

8.28. Based on the Staff Report and other information provided to the Committee by the applicant and submitters, the Committee considered that with the controls proposed in place the impact of the substance 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.

Assessment of risks to society, the community and the economy

8.29. The Committee did not identify any possible risks to society, the community and the economy. The Committee therefore did not consider this further.

9. Consideration of best international practices and standards

9.1. 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.

9.2. The Committee specifically noted that it is standard international practice to set buffer zones as a mechanism for reducing spray drift onto sensitive areas. They noted that the uncertainty around determination of appropriate buffer zone sizes for all types of topography for Exirel® application precluded the use of buffer zones to mitigate risks to aquatic organisms.

10. Decision

10.1. Pursuant to sections 7 and 63A(6) of the Act and section 32 of the Methodology, the Committee considered this application to modify an approval for an amendment. In doing so, the Committee applied all the relevant sections of the Act and clauses of the Hazardous Substances and New Organisms (Methodology) Order 1998 ("the Methodology").

10.2. The Committee considered that the benefits of the reassessment to allow aerial application of Exirel® are negligible. The Committee considered that the effects on aquatic organisms given the degree of uncertainty surrounding determination of appropriate buffer zones necessitates a decline of the application in accordance with sections 7 and 63A of the Act.

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

10.4. Consequently, the Committee determined that the application be declined and no amendments made to approval HSR100857.

Dr John Taylor	**Date: 1 September 2016**
Chair, Decision Making Committee Environmental Protection Authority	