



ASSESSMENT OF PROPOSAL FOR AMENDMENT

Application proposed to be amended	APP201858
Approval holder	University of Otago
Purpose of the approval	To import into containment new organisms under section 40(1) of the Hazardous Substances and New Organisms (HSNO) Act 1996
Date of approval	2 March 2015
Amendment number	APP204164
Purpose of the amendment	To add host organisms to the existing approval list of organisms.
Amendment applicant	University of Otago
Date of advice	6 April 2021

Summary

The University of Otago applied to the EPA to amend their existing approval, APP201858, to include new host organisms for genetic modifications for research purposes.

Introduction

1. The University of Otago (the approval holder) was granted an approval in 2015 to import into containment a range of non genetically modified organisms and genetically modified non-pathogenic microorganisms, cell lines, plants and animals.
2. The current controls for APP201858 require the approval holder to contain the approved microorganisms within a containment facility that complies with the MAF/ERMA New Zealand Standards.
3. We noted that the approval APP201858 has not been amended before.
4. The original application was not publicly notified as it was not considered to meet the threshold of significant public interest because the new organisms are not novel to New Zealand, and all research and teaching involving the new organisms would be conducted within containment facilities.

Legislative criteria and EPA guidance

5. Any approval may be amended under section 67A of the Hazardous Substances and New Organisms Act 1996 (HSNO Act), provided the change is minor in effect or corrects a minor or technical error.
6. A “minor error” is likely to be an error (a mistake) that is thought to be comparatively unimportant or insignificant. A “technical error” may include typographical or drafting errors related to a technical aspect of the approval and are not restricted to “minor” technical errors. Changes that are “minor in effect” may include alterations that do not significantly increase risks, especially those risks that are associated with the organism, and on the parties involved.
7. This proposed amendment is minor in effect and the amended decision will confirm that the applicant is able to import into containment an extensive list of low-risk, category 2 organisms.
8. The decision path for the s67A amendment is provided as Appendix 1 of this document.

Assessment of the proposal

9. The approval currently allows the importation of approved low-risk, category 2 microorganisms, cell lines, plants and animals in PC1 and PC2 containment. The proposed amendment is to broaden the range of approved low-risk, category 2 organisms which fit within the scope of the approval. Appendix 2 contains the full list of proposed species.
10. The amendment will exclude any organisms listed as unwanted organisms to avoid increasing the overall risk profile of the original containment approval.
11. The previous approval contained *Trifolium occidentale* and *T. repens*. As the applicant seeks the addition of all *Trifolium* species, we have elected to remove these two species and instead list ‘*Trifolium* species’ to cover all species within this genus.
12. Facilities carrying out research under the Regulations must comply with the controls set out in a HSNO Act approval. These controls specify the approved organisms and the standard to which the containment facility using the HSNO Act approval needs to be approved.

13. The applicant has not provided information regarding consultation with Māori as no concerns were raised in previous consultations with Ngāi Tahu iwi and the University of Otago's Institutional Biological Safety Committee (IBSC) about the use of the original approval on the University's Dunedin and Christchurch campus.

Assessment conclusion

14. In assessing whether the proposed amendment meets the criteria required under s67A of the HSNO Act, we conclude that the amendment is minor in effect, as there is no change to the scope of the approval or in the risk posed by the addition of low-risk, category 2 organisms and the controls provide for suitable containment of the organisms.
15. We did not identify any cumulative effects resulting from the current proposed amendment and further, the amendment will not change the risk profile of the original approval.
16. Therefore, we recommend that it is appropriate to amend this approval under section 67A of the HSNO Act as the amendment is minor in effect.
17. The proposed amendment may be achieved by the addition of low-risk, category 2 organisms. We have provided an approval document with tracked changes to highlight the required changes, should you approve the amendment.

Matters in Part 2 of the Act

18. The proposed amendment relates to an approval for the importation of low-risk, category 2 genetically modified organisms into a containment facility. The proposed amendment is minor in effect and will not alter the risks of this research. As such, we do not consider that the purpose, principles or matters to be considered (sections 4-8 of the HSNO Act) would be adversely affected by the proposed amendment.

Consultation

19. The Ministry for Primary Industries (MPI) and the Department of Conservation (DOC) were consulted regarding the proposed amendment.
20. MPI supports the amendment through the addition of a number of low-risk (Category 2) host organisms and also the exclusion of the unwanted organism, *Gunnera tinctoria*. MPI considers that the provisions of the current approval is adequate to ensure that the additional genetically modified organisms are able to be contained and the risks of escape managed.
21. DOC considered the amendment to carry very low risks to biodiversity and that the species proposed for addition are already present in New Zealand. DOC stated that they are not opposed to the approval of this application.

Recommendation

22. We recommend that you approve the amendment of the decision document for application APP204164 under section 67A of the HSNO Act, to broaden the range of approved low-risk, category 2 genetically modified organisms which fit within the scope of the approval.

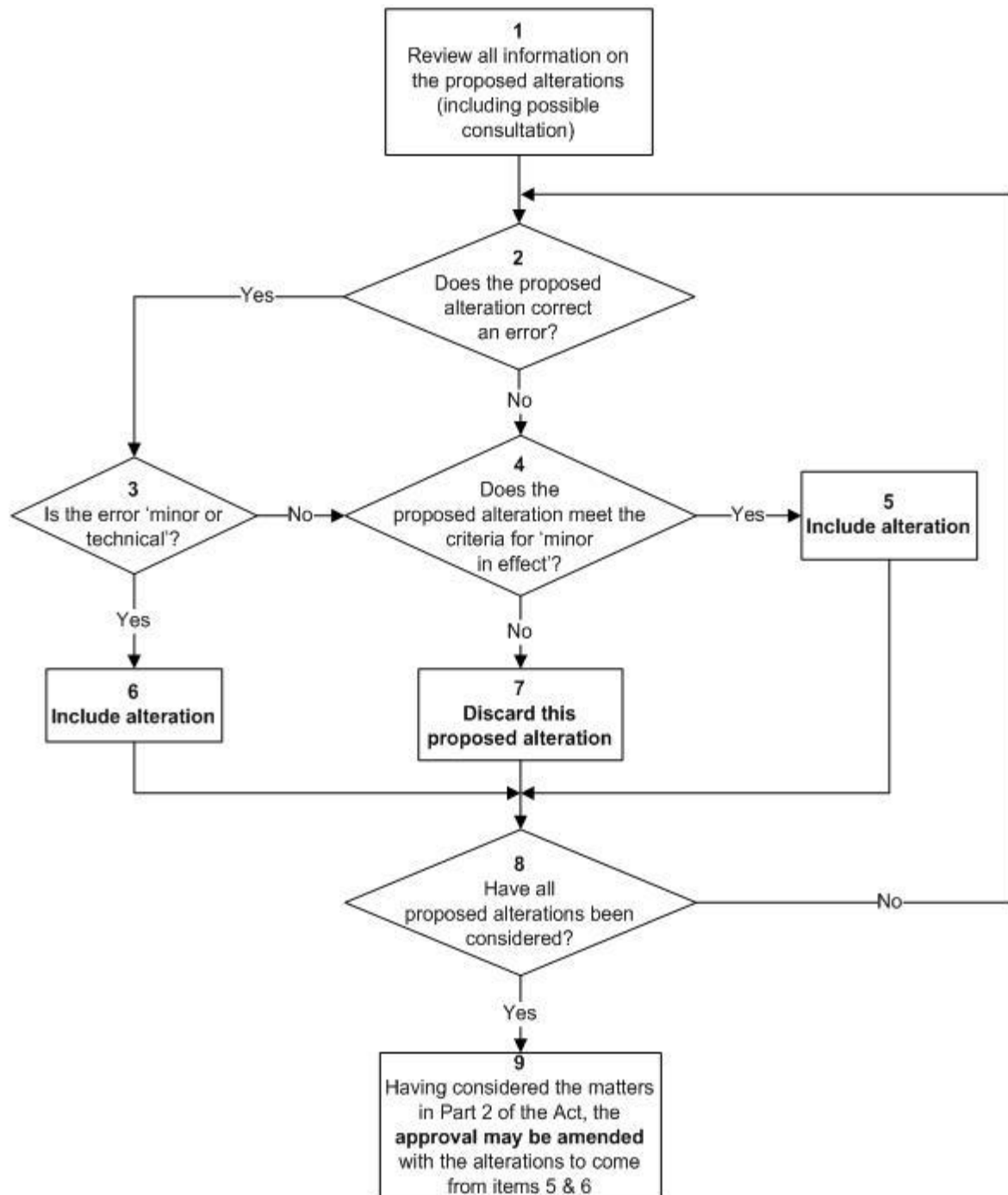


6 April 2021

Advisor, New Organisms Date
Hazardous Substances and New Organisms

Appendix 1: Flowchart: Decision path for consideration of amendments to existing approvals that are 'minor in effect' or to correct a 'minor or technical error' under section 67A of the HSNO Act, and explanatory notes

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



Explanatory Notes

<p>Item 1:</p>	<p>Review all information on the proposed alterations (including possible consultation)</p> <p>Review all information, including any information provided by other agencies or experts. This should enable the HSNO decision maker to clearly evaluate the proposed alteration(s) against the criteria set out in section 67A for making an amendment, namely whether the HSNO decision maker considers the amendment to be 'minor in effect' or to correct a 'minor or technical error'.</p>
<p>Item 2:</p>	<p>Does the proposed alteration correct an error?</p> <p>Taking each proposed alteration in this category in turn, review whether the alteration corrects an error. An 'error' can be described as something done incorrectly because of ignorance or inadvertence: a mistake</p>
<p>Item 3:</p>	<p>(if 'yes' from item 2) Is the error 'minor or technical'?</p> <p>If the proposed alteration is to correct an error, consider whether the error meets the criteria for 'minor or technical error', as described with detail in the Key Concepts protocol "Minor in effect' or 'minor or technical error'".</p>
<p>Item 4:</p>	<p>(if 'no' from item 2 or 3) Does the proposed alteration meet the criteria for 'minor in effect'?</p> <p>If the proposed alteration does not correct a 'minor or technical' error, consider whether the alteration meets the criteria for 'minor in effect' as described with detail in the Key Concepts protocol "Minor in effect' or 'minor or technical error'"¹.</p> <p>If a proposed alteration meets the criteria for 'minor in effect', continue to item 5. If any of the proposed alterations do not meet these criteria move to item 7 and discard the proposed alterations. While these are unable to be considered under section 67A, it may be appropriate for them to be resubmitted as an application under section 63A for hazardous substances (modified reassessment) or section 63 for both hazardous substances and new organisms (full reassessment).</p>
<p>Item 5:</p>	<p>(if 'yes' from item 4) Include alteration</p> <p>If the proposed alteration meets the criteria for 'minor in effect', include this alteration for final consideration and confirmation in item 9, and continue to item 8.</p>
<p>Item 6:</p>	<p>(if 'yes' from item 3) Include alteration</p> <p>If the proposed alteration meets the criteria for correcting a 'minor or technical error', include this alteration for final consideration and confirmation in item 9, and continue to item 8.</p>
<p>Item 7:</p>	<p>(if 'no' from item 4) Discard this proposed alteration</p> <p>If the proposed alteration did not meet the criteria for correcting a 'minor or technical error' or 'minor in effect', discard this proposed alteration and do not consider it further.</p>
<p>Item 8:</p>	<p>Have all proposed alterations been considered?</p>

¹ <http://www.epa.govt.nz/Publications/ER-PR-03-22-Key-Concepts-Master-File.pdf>.

	<p>Check whether all the proposed alterations for 'minor in effect' and to correct a 'minor or technical error' have been considered. If not, then return to item 2 and consider the remaining alterations. If all proposed alterations have been considered, continue to item 9.</p>
Item 9:	<p>(if 'yes' from item 8) Having considered the matters in Part 2 of the Act, the approval may be amended with the alterations to come from items 5 & 6.</p> <p>Considering each alteration identified in items 5 and 6 that has met the criteria specified in section 67A, review in terms of the matters described in Part 2 of the Act and decide whether to make the alteration, noting that the Authority retains the discretion as to whether or not to make the alteration.</p> <p>Once consideration has been given to all alterations that have met the criteria, the approval may be amended.</p>

Appendix 2: List of proposed organisms for approval.

Organism	Approval number
<i>Physcomitrella patens</i> Bruch & W.P.Schimper, 1849	
<i>Pisum sativum</i> L.	
<i>Marchantia polymorpha</i> L.	
<i>Anthoceros</i> species L.	
<i>Azolla</i> species Lam.	
<i>Avena sativa</i> L.	
<i>Bromus</i> species Scop.	
<i>Dactylis</i> species L.	
<i>Festuca</i> species L.	
<i>Hordeum vulgare</i> L.	
<i>Secale cereale</i> L.	
<i>Triticum</i> species L.	
<i>Allium sativum</i> L.	
<i>Allium porrum</i> Georgi	
<i>Arabidopsis lyrata</i> (L.) O'Kane & Al-Shehbaz	
<i>Brassica oleracea</i> L.	
<i>Brassica napus</i> L.	
<i>Brassica rapa</i> L.	
<i>Solanum tuberosum</i> L.	
<i>Solanum betaceum</i> Cav.	
<i>Trifolium</i> species L.	
<i>Lathyrus ororatus</i> L.	
<i>Glycine max</i> (L.) Merr.	
<i>Rubus</i> species L.	
<i>Fragaria vesca</i> L.	
<i>Fragaria x ananassa</i> Duchesne	
<i>Malus domestica</i> Borkh	
<i>Beta vulgaris</i> L.	
<i>Plantago lanceolata</i> L.	
<i>Cichorium intybus</i> L.	
<i>Gunnera</i> species L. except <i>G. tinctoria</i> (Molina) Mirb.	

Organism	Approval number
<i>Actinidia deliciosa</i> (Chev.) C.F.Liang & A.R.Ferguson	
<i>Actinidia chinensis</i> Planch.	
<i>Actinidia argute</i> Miq.	
<i>Vitis vinifera</i> L.	
<i>Vaccinium myrtillus</i> L.	
<i>Daucus carota</i> L.	
<i>Nasonia vitripennis</i> (Walker, 1836)	
<i>Microctonus aethiopoides</i> Loan	
<i>Microctonus hyperodae</i> Loan, 1974	