



## ASSESSMENT OF PROPOSAL FOR AMENDMENT

Assessment of proposal for amendment under section 67A of the HSNO Act 1996

<b>Application Number</b>	NOC05006
<b>Approval Holder</b>	Institute of Geological & Nuclear Sciences
<b>Purpose of the Approval</b>	This application is for the importation for research purposes including taxonomy, ecology, biodiversity and biotechnology studies, of groups of non-pathogenic extremophilic microorganisms
<b>Date of Approval</b>	20 October 2005
<b>Amendment Number</b>	APP203756
<b>Purpose of the Amendment</b>	To correct a technical error in the description of the scope of the approval set out in the decision on the application numbered NOC05006 (which relates to non-pathogenic, extremophilic microorganisms)
<b>Date of Amendment request</b>	16 November 2018

### Background

1. The application NOC05006 from the Institute of Geological & Nuclear Sciences to import non-pathogenic extremophilic microorganisms, not genetically modified, into containment was approved with controls in 2005 (the '**decision**'). The purpose of the application was to use the microorganisms as a reference collection to allow identification of isolates recovered from the New Zealand environment. In addition, basic ecological studies were to be undertaken to better understand the biology of the potentially valuable organisms.
2. The decision was amended for the first time by ERMA on 6 September 2006 to alter the controls pursuant to s67A of the Hazardous Substances and New Organisms (HSNO) Act 1996 (HSNO Act).

### Amendment Proposed and Reason

3. The Environmental Protection Authority (EPA) is seeking to amend the decision pursuant to section 67A of HSNO Act to correct a technical error in the expression of the scope of the containment approval at paragraph 1.1, by adding a sentence to make clear that the approval applies only to non-pathogenic extremophilic microorganisms which do not belong to a species that was present in New Zealand immediately before 29 July 1998.

4. It is also proposed to set out a summary of the decision (as amended, as set out herein) as a separate document to be published on the EPA website, setting out the amended summary of the decision at paragraph 1.1 of the decision, along with the Appendix 1 controls. The Appendix 1 controls are not being updated and would be set out in their current form. This will improve clarity as to the scope of the approval.
5. The reason for proposing the amendment is that, as currently drafted, the decision summary at paragraph 1.1 appears to provide for a broad containment approval which applies regardless as to whether or not the organisms were present in New Zealand immediately before 29 July 1998.
6. It is apparent that the full text of the decision, in line with the EPA's authority under the HSNO Act, provides for an approval in connection with those non-pathogenic, extremophilic microorganisms which are 'new organisms' in that they were not present in New Zealand immediately before 29 July 1998.
7. It is therefore proposed to amend paragraph 1.1 which sets out the summary of the decision by adding the following new sentence as the final sentence of that paragraph: 'This approval applies only to non-pathogenic, extremophilic microorganisms that were not present in New Zealand immediately before 29 July 1998.' The above amendment will correct the drafting error in that paragraph and improve clarity as to which organisms are under this containment approval.
8. The proposal was formally received on 08 July 2019 and will be determined by an EPA Decision-Making Committee (DMC) in accordance with powers delegated by the Authority under section 19(2)(b) of the HSNO Act.

### Legislative criteria for amendment

9. Section 67A provides that the 'Authority may, of its own motion, amend any approval given by it under this Part if it considers that the alteration is minor in effect or corrects a minor or technical error'.
10. A technical error may include typographical or drafting errors related to a technical aspect of the approval. An example of a technical error may be an error made in the formal identity of an organism. Section 67A does not restrict the interpretation of a technical error to being minor.
11. The decision path for the s67A amendment is provided as Appendix 1 of this document.

### Assessment of the proposed amendment

12. The summary of the decision states that the 'application to import into containment "non-pathogenic extremophilic microorganisms" is approved with controls (as detailed in Appendix 1 of this decision)'. On its face, the summary of the decision at paragraph 1.1 would appear to extend the approval to any non-pathogenic microorganisms (i.e. regardless as to whether or not they were present in New Zealand immediately before 29 July 1998).
13. However, in section 5.1 of the decision, the purpose of the application is stated to have been for the applicant 'to import a number of non-pathogenic extremophilic microorganisms for use as a reference collection to allow identification of isolates recovered from the New Zealand environment. In addition, basic ecological studies will be undertaken to better understand the biology of these potentially valuable

organisms'. The implication is that there are isolates of non-pathogenic extremophilic microorganisms in New Zealand environment.

14. Further, in considering the potential for the organisms to cause adverse effects to the environment, the Committee notes at paragraph 8.3 of the decision that "[i]n order for an adverse effect to be realised the escaped microorganism would need to out-compete the existing microflora for resources resulting in displacement. In conducting this assessment the Committee recognised that there is a high probability, given the highly specialised nature of these microorganisms, that they may already be present in these environments."
15. On review of the full text of the decision, it is apparent that the approval was given with the acknowledgement that it was highly probable that non-pathogenic extremophilic microorganisms were existing already in New Zealand, although there is no determination within the decision as to which specific non-pathogenic extremophilic microorganisms were to fall within the scope of the approval.
16. The decision provides via 'controls' that the onus is on the person seeking to rely on the approval in each instance to identify the relevant microorganism as 'non-pathogenic' and as an extremophilic microorganism during importation through labelling. The approval would only apply where this control is met. Any person wishing to rely on the approval would effectively assert that they wished to do so by complying with the controls set out within the approval.
17. The above points are consistent with the scope of the approval to be for any 'non-pathogenic extremophilic microorganisms' which were 'new organisms' in that they 'belong to a species that was not present in New Zealand immediately before 29 July 1998'.
18. The error could be resolved by amending the summary to clarify that the approval applies only to non-pathogenic, extremophilic microorganisms that were not present in New Zealand immediately before 29 July 1998.
19. I do not consider that the amendment to the decision as outlined above would change the risk profile of the decision, as it will amend the drafting to correctly reflect the technical description of what is covered by the decision in accordance with the HSNO Act and the decision as set out in its text in full.
20. I have provided the Decision Maker with the amended approval with the amended text in red.

## Recommendation

21. I recommend you approve this proposed amendment and publication of a summary of the approval as outlined in sections 3 and 4.

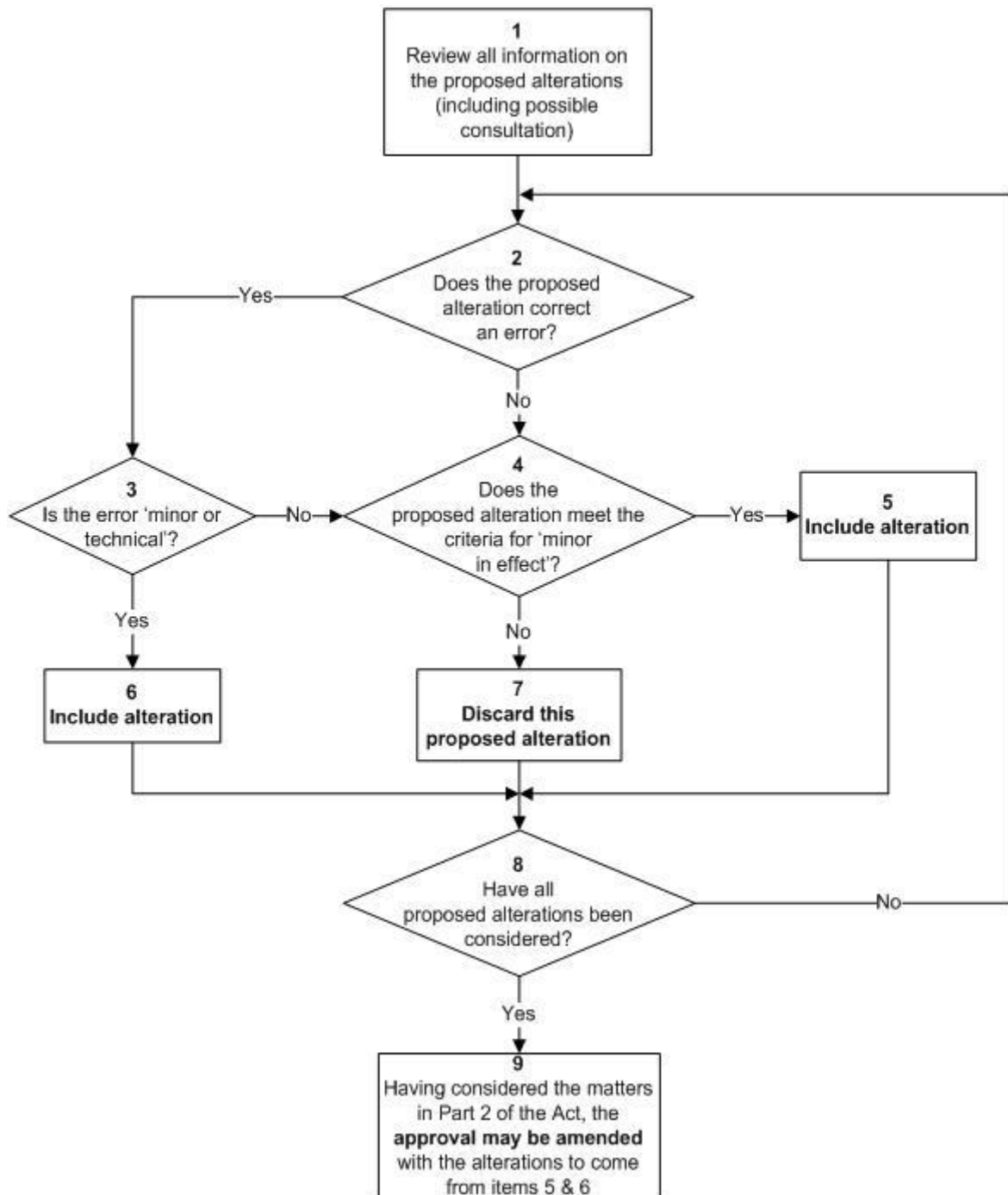
04 July 2019

██████████ Advisor  
New Organisms

Date

Appendix 1: Figure 23 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.



## Figure 23 Explanatory Notes

<b>Item 1:</b>	<b>Review all information on the proposed alterations (including possible consultation)</b> 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'.
<b>Item 2:</b>	<b>Does the proposed alteration correct an error?</b> 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
<b>Item 3:</b>	<b>(if 'yes' from item 2) Is the error 'minor or technical'?</b> 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'".
<b>Item 4:</b>	<b>(if 'no' from item 2 or 3) Does the proposed alteration meet the criteria for 'minor in effect'?</b> 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'" ( <a href="http://www.epa.govt.nz/Publications/ER-PR-03-22-Key-Concepts-Master-File.pdf">http://www.epa.govt.nz/Publications/ER-PR-03-22-Key-Concepts-Master-File.pdf</a> ). 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).
<b>Item 5:</b>	<b>(if 'yes' from item 4) Include alteration</b> 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.
<b>Item 6:</b>	<b>(if 'yes' from item 3) Include alteration</b> 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.
<b>Item 7:</b>	<b>(if 'no' from item 4) Discard this proposed alteration</b> 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.
<b>Item 8:</b>	<b>Have all proposed alterations been considered?</b> 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.
<b>Item 9:</b>	<b>(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 &amp; 6.</b> 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. Once consideration has been given to all alterations that have met the criteria, the approval may be amended.