

# REQUIREMENTS FOR CONSULTATION WITH MĀORI ON HSNO APPLICATIONS THAT INVOLVE HUMAN CELL LINES AND/OR HUMAN DNA

## Introduction

1. The policy set out below applies to applications made within the requirements of the HSNO Act for the import, development and/or use of genetically modified human cell lines, or to the import, development, field test or release of genetically modified organism which contain copies of human DNA.
2. Applications of this kind may be made to the Authority, the Chief Executive of ERMA New Zealand, or others with a delegation provided by the Authority, referred to for the purposes of this policy as the ‘decision maker’. The requirements outlined below apply regardless of the appointed ‘decision maker’.

## Requirements for Consultation

3. In terms of this policy, ‘consultation’ is defined as:  
*“a process of genuine and informed dialogue intended to create understanding and knowledge of the views of the parties on a particular subject”*
4. The obligation to consult rests primarily with the applicant. If consultation is not in conformity with the guidelines provided, the decision maker should either decline the application or invite the applicant to withdraw the application, correct the deficiency and resubmit.
5. Consultation is a two way (at least) process. The obligation to consult requires that every reasonable endeavour is made to do so. Reasonable endeavours require multiple attempts to establish dialogue including the offer and undertaking of face to face meetings where they are requested. However, it is accepted that on occasion reasonable endeavours will not succeed and, under those circumstances, the obligation shall be considered to have been discharged.
6. Applications requiring consultation will need to include evidence of the consultation including attempts made to establish dialogue, feedback obtained during consultation and any outcomes of relevance to decision making.

## Circumstances Requiring Consultation

### Source of Material

7. The requirements outlined apply to the import, development and use of human cell lines and/or human DNA both as host or donor organism.

8. Consultation with Māori must occur where human cell lines or human DNA is sourced directly from known individuals, if they are of Māori whakapapa or origin<sup>1</sup>. This requirement applies to both imports and developments.
9. Consultation with Māori is not required if the DNA or cells are sourced from non-Māori, provided that this is satisfactory to the individual concerned and provided that general ethics requirements are met (e.g. prior informed consent).
10. Applications involving the import or development of human cell lines obtained commercially, or DNA sourced from libraries where origin is either not of Māori whakapapa or not known, will not require consultation, subject to meeting the terms of paragraph 11, 12 and 13 below. However, applicants will need to provide the following information as part of their application:
  - Any Ethics Committee approval information where relevant; and
  - Source of the human cell lines or DNA (e.g. the name and details of the supplier).

### **Nature of Application**

11. Where applications include laboratory based research involving standard comparative or biomedical studies, consultation with Māori will not be required unless the human cell lines or DNA is derived directly from humans of Māori whakapapa / origin (as noted above).
12. Consultation with Māori will be required regardless of the source of the human cell lines or DNA, where applications are very likely to lead to outdoor development, field test or release including conditional release. Consultation with Māori is also required if a GMO containing a copy of human DNA is to be a part of a field test, a conditional release or a full release irrespective of whether consultation already occurred at a prior development or import into containment stage.
13. Consultation will also be required for applications involving the import, development or use of genetically modified human embryonic stem cells, regardless of the source of those stem cells.

### **Dealing with the Results of Consultation**

14. The results of formal consultation must be dealt with as follows:
  - a) The details and outcomes of consultation must be well recorded in the application.
  - b) Where iwi/Māori request special conditions to be imposed for cultural reasons, then as far as is judged practicable by the decision maker those requests should be

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<sup>1</sup> Māori whakapapa or origin is determined through the self identification of the donor.

incorporated. Consideration of what is practicable is likely to vary between applications and will require case by case consideration.

NB: Where uncertainty exists about what is 'practicable', advice can be sought from ERMA New Zealand.

- c) Where the decision maker is operating within the terms of a delegation from the Authority, an application must be either declined or referred to the Authority for assessment if Māori objections to the application continue following consultation, and the provision of proposals to apply specific conditions designed to address those objections. This does not apply if the objection is of a general nature i.e. an objection to genetic modification generally.

15. Further guidance on dealing with the results of consultation can be found in the ERMA New Zealand protocol *Incorporating Māori Perspectives in Part V Decision Making*.