

**Requirements for Delegation of Power to Conduct Rapid Assessments of Applications
for Development in Containment and Importation into Containment of Low Risk
Genetically Modified Organisms**

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1 Purpose

The Environmental Risk Management Authority (the Authority) may at its discretion delegate, under section 19(2)(a), the power to conduct rapid assessment of applications to develop in containment or import into containment low risk genetically modified organisms (GMOs) in accordance with sections 42, 42A, and 42B of the Hazardous Substances and New Organisms (HSNO) Act 1996. All such delegations shall be exercised in accordance with the provisions of this document.

2 Introduction

Applications to develop in containment or import into containment genetically modified organisms (GMOs) meeting the low risk criteria established in the HSNO (Low-Risk Genetic Modification) Regulations 2003 (as amended) (the Regulations) may be rapidly assessed by Institutional Biological Safety Committees (IBSCs). The Regulations provide for three categories (Categories A, B, and “not low risk”) of genetic modification work. Experiments falling into Categories A and B are low risk genetic modifications, assessments which the Authority may delegate. The following procedures and requirements outline the conditions in which the institutions are delegated the power to conduct rapid assessments of applications to develop and import into containment, low risk GMOs.

3 Responsibilities of the Chief Executive Officer

The Chief Executive Officer (CEO) or equivalent of the institution will be responsible for ensuring that these requirements are complied with. The CEO shall:

- ensure that the institution establishes an Institutional Biological Safety Committee (IBSC) to advise on the assessment and determination of applications for developments in containment and importations into containment of low risk GMOs;
- ensure that the institution provides the IBSC with such resources and facilities as necessary for performing its functions under these requirements;
- recognise the vital role of the IBSC and give it the authority and support required to carry out its duties; and
- take steps to actively ensure that persons within the institution developing, importing, field testing or releasing GMOs are aware of their obligations under the HSNO Act 1996, and seek and obtain the necessary HSNO approvals for such work.

The Institution may establish more than one IBSC each with jurisdiction over one specific site, however, each IBSC shall comply with the terms of the delegation to the Institution. Establishment of additional IBSCs shall be done in consultation with ERMA New Zealand.

The Authority recognises the difficulties that smaller institutions may face when setting up an IBSC. It is anticipated that these smaller institutions may be assisted by an appropriate IBSC from another institution or directly by the Authority if there is a need to avoid conflict of interest between institutions. Between-institution arrangements shall be formalised by the institutions concerned, and notified to the Authority. It is desirable that a senior member of the smaller institution shall liaise closely with, and be a member of, the appropriate IBSC. The Authority may facilitate these arrangements as appropriate. In the situation where both institutions do not wish the smaller institution to be a member of the IBSC, documented evidence to this effect must be supplied to ERMA New Zealand

The decisions made by the institution, on the advice of the IBSC, shall be treated in all respects as though they were decisions made by the Authority within the limitations specified in the Act. If the IBSC advises that it is unable to recommend a decision on a particular application or if the application is declined, the application may be referred to the Authority for full assessment (and relevant fees will apply).

4 Composition of the IBSC

The IBSCs may need to co-opt additional experts as members to ensure that the expertise listed below is available for its assessment of applications under the delegation. Roles and responsibilities may be combined in the same person where appropriate.

The IBSC shall include:

- i) persons with the requisite knowledge and expertise to assess, evaluate and oversee work being carried out in the institution;
- ii) a Chairperson;
- iii) a Biological Safety Officer who is not the Chairperson;
- iv) at least one lay person, not associated with the institution, who is in a position to consider wider community interests;
- v) a microbiologist;
- vi) a molecular biologist; and/or
- vii) a geneticist; plus
- viii) an ecologist with expertise relevant to the type of organism (i.e. plant, animal, micro-organism) to be developed; and
- ix) at least one Māori representative (unless an exemption applies) mandated by hapū or iwi with appropriate mana whenua¹ in the locality of the IBSC.

The scientific disciplines need only be represented where work falling into that area is to be assessed. For example, an institution working on plants need not have an animal geneticist.

It is acceptable for several of these requirements to be met by one individual if an individual with that breadth of expertise is available, except, when otherwise stipulated above. However, the IBSC shall contain at least five members for each consideration. The committee shall aim to achieve consensus decision-making and where this is not possible majority decision-making shall apply.

5 Chairperson

The chairperson of the IBSC shall be of sufficient standing in the institution for decisions to be effectively made and implemented. The Authority will need to satisfy itself that the Chairman of the IBSC has a thorough familiarity with the HSNO decision-making process,

¹ Mana whenua is defined in this context as all those iwi or hapū who have customary authority through whakapapa, ahi ka roa (long standing occupation) and/or who are well recognised in the broad geographical region of the IBSC.

including the HSNO Act, the HSNO (Low-Risk Genetic Modification) Regulations 2003, the Methodology, and the terms of delegation. At the very least, there needs to be written confirmation or a past history that the IBSC is aware of and has actively referred to these documents.

6 Biological Safety Officer

The Institution shall appoint for each IBSC, a Biological Safety Officer (BSO). The BSO shall:

- have experience of working with containment conditions;
- have the responsibility of notifying any IBSC membership changes or other significant changes in the institution (including changes to Vice Chancellor or CEO) to the Authority; and
- the Authority will need to satisfy itself that the Biological Safety Officer for the IBSC has a thorough familiarity with the HSNO decision-making process, including the HSNO Act, the HSNO (Low-Risk Genetic Modification) Regulations 2003, the Methodology, and the terms of delegation. At the very least, there needs to be written confirmation or a past history that the IBSC is aware of and has actively referred to these documents.

The institution shall put in place appropriate deputising arrangements for when the BSO is on leave or otherwise unavailable.

7 Criteria for assessment

Criteria for determining if genetic modifications are considered low risk are set out in the HSNO (Low-Risk Genetic Modification) Regulations 2003. The containment requirements are set out in the AS/NZS 2243.3:2002 Australian New Zealand Standard: Safety in Laboratories, Part 3: Microbiological aspects and containment facilities referred to in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003. Assessment of applications should be in accordance with the Methodology approved under section 9 of the HSNO Act 1996 and the protocols developed by the Authority. Applications that are not for low risk genetic modifications must either be withdrawn or referred to the Authority for consideration.

8 Dealing with ethical issues

Applications may be received that raise ethical issues, such as the use of human genes in genetically modified organisms. The institution should consider this when applications are received and take appropriate action if ethical issues are involved. It is at the discretion of each institution to consider what action to take, although it is recommended that IBSCs consider the informal guidelines set out in the ERMA New Zealand NZ Protocol ER-PR-05-12/05 "*Ethics Framework*".

The institution shall have written procedures on how applications involving human ethical or animal ethical/welfare issues will be addressed and the procedures adopted in each situation should be documented. These procedures might include the institution ensuring that there is independent representation on the IBSC that can advise on ethical issues, or seeking advice from, for example, a medical ethics committee. The IBSC may also advise the institution to refer applications to the Authority if it considers the issues are serious enough to warrant this.

The Authority advises that, as a minimum, the applicants shall obtain appropriate ethics committee approvals where DNA from humans is involved in the genetic modification experiments. There are additional requirements to meet Māori concerns where DNA is sourced directly from individuals identifying themselves as Māori (see section 10).

The ethical guidelines promulgated by the Health Research Council shall apply in all cases where those guidelines are relevant.

9 Māori Consultation

It cannot be too strongly emphasised that the best way to deal with Māori concerns and interests is through the establishment of a mutually acceptable, constructive and long term relationship with the local Māori community. It is important to recognise the circumstances in which it is either necessary or desirable to consult Māori. Detailed advice on when consultation is required and how best to consult with Māori is set out in a separate User Guide “*Working with Māori under the HSNO Act 1996: A Guide for Applicants*”. In addition, our policy, “*Māori Membership of Institutional Biological Safety Committees (IBSCs) and Consultation Requirements with the Māori Community*” provides further guidelines for Māori consultation, specifically applications qualifying for IBSC consideration. Both are available from ERMA New Zealand or on our web site. The Authority may from time to time amend its policy on Māori consultation. Delegates will be notified in writing of any changes in policy.

The inclusion of mandated Māori member(s) on the IBSC committee should facilitate a good working relationship between the IBSC and the local iwi community. In some localities relationships will be harder to establish than others. If you need help, do not hesitate to contact our General Manager, Māori at ERMA New Zealand.

A distinction can be drawn between consulting on the one hand and informing or discussing on the other. Consultation is a two-way process carrying with it a clear expectation that the results of the consultation will provide input to and thus may influence a decision. Informing and discussing does not carry with it the same level of expectation.

Consultation requires every reasonable effort on the part of the party consulting (the applicant) and a willingness to respond reasonably on the part of those consulted. The current approach is that the test of ‘reasonableness’ will if necessary be applied by the Authority in determining whether consultation has been appropriate or adequate.

Limits to the authority of the mandated Māori member

The need to consult will be waived if the mandated Māori member(s) on the IBSC committee is able and prepared to speak on behalf of the local hapū or iwi, and concerns over the application are relevant to the locality of that hapū or iwi.

However, consultation **will** be required if an iwi or hapū outside of the locality is involved and the Māori member(s) do not have a mandate to deal with their concerns. A typical case is that of research being done within one IBSC's local area involving DNA from a species from another geographical region. In this case, hapū or iwi from both localities must be involved. Where the IBSC wishes to transfer the approval to other localities, the relevant hapū or iwi will need to be consulted. More information about these requirements is again found in our policy "*Māori Membership of Institutional Biological Safety Committees (IBSCs) and Consultation Requirements with the Māori Community*".

Dealing with the results of consultation

If Māori are consulted, or express a view through a mandated member(s) and object to the work proceeding then the following actions must be taken:

- where Māori want special conditions to be incorporated to overcome cultural objections, then as far as is practicable those requests should be complied with. The question of what is practicable will vary from case to case. If the conditions desired are unreasonable or impracticable then the reasons must be recorded.
- if Māori object to the work, even after applying conditions, and provided that the objection is not a general objection to genetic modification, then the IBSC must either decline the application or refer it to the Authority for a full assessment. The full assessment process will then give the Authority an opportunity to look at both the benefits and the costs of the application.

10 Conflicts of interest

Members of the IBSC shall not advise on their own applications, nor of those they are closely associated with. The IBSC must have sufficient scientific members, or co-opt them as required to allow for this. To avoid conflicts of interest (professional or commercial), final decisions on applications shall be made in the absence of the applicant. The BSO in consultation with the IBSC shall notify all conflicts of interest and their resolution to the Authority within 20 working days of the conflict of interest becoming known. The consideration of the application shall not proceed if the matter cannot be resolved but may be referred to the Authority for consideration.

11 Monitoring of decisions

The Authority or its authorised agent will from time to time visit institutions, which have delegated authority and will review the decision-making activities of the institution. The institution shall provide reasonable access to personnel, records and laboratories for this purpose, and pay any auditing fees as may be applicable.

12 Duties of the IBSC in advising institutions under this delegation

The main duties of the IBSC are to:

- i) advise on the determination of the application in accordance with the HSNO Act 1996, Methodology and any relevant supporting protocols issued by ERMA New Zealand;
- ii) ensure compliance with the Authority's requirements;
- iii) take into account the relationship of Māori with their taonga (section 6d of the HSNO Act 1996) in the consideration of applications. This will include evaluating applications that raise matters of concern to Māori (see section 9) in accordance with these conditions and the more general guidance provided in the Protocol: "*Incorporating Māori Perspectives in Part V Decision Making*", which outlines how decision-makers under the HSNO Act 1996 will evaluate applications of importance to Māori;
- iv) advise applicants that all applications involving native flora and fauna or flora and fauna identified as valued (excluding microorganisms) shall require information on the effects on the relationship of Māori and their culture with their taonga (refer to the user guide "*Working with Māori under the HSNO Act 1996: A Guide for Applicants*");
- v) establish and maintain relationships with the local hapū or iwi, where institutions are likely to require information on the effects of any applications on the relationship of Māori with their taonga;
- vi) ensure that applications involving human genes or animals have appropriate ethical and welfare consideration and approvals;
- vii) undertake assessment within 10 working days of the receipt of application (with waivers of this time as necessary to allow additional information to be provided) in accordance with the delegation by the Authority, in order to identify all potential effects to people, the community and the environment;
- viii) send copies of applications, including declined applications, and the completed decision forms, made under the delegation to the Authority within 10 working days of making the decision;
- ix) advise on the determination of containment and procedures for all experimental work falling into Categories A and B, and for the housing, storage and transportation of GMOs falling under the delegation;
- x) send all applications for experiments falling outside categories A and B of the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003 to the Authority. If an experiment falls into the "not low risk" schedule, it shall not be considered by the IBSC, but referred to the Authority for consideration. Applications should also be referred to the Authority if Māori cultural objections have been raised through consultation, and these objections are not able to be met through the setting of controls or by declining the application;
- xi) maintain a register of approved experiments under this delegation; and
- xii) refer matters of conflict of interest and its resolution to the Authority within 20 working days of it becoming known;

13 Reporting requirements

At the time of establishment of the IBSC and once a year thereafter at conclusion of each calendar year, the BSO in consultation with the IBSC shall provide the Authority with the following details:

- location and name of IBSC;
- names of chairperson of the IBSC;
- and biological safety officer;
- names of members of the IBSC and their role/expertise, noting any changes since the previous annual report;
- a complete list of applications and decisions, including declined applications, made under the delegation and the members of the committee if different from above;
- any anticipated changes to the scope and nature of GM developments likely to be considered by the IBSC in the forthcoming year; and
- any other matter which the institution wishes to draw the Authority's attention to.

14 Sanctions

Non-compliance with these requirements or any directive of the Authority may result in revocation of the delegated power by the Authority.