

**Criteria for Delegating Power to Conduct Rapid Assessments of Applications for the Development in Containment and Importation into Containment of Low Risk Genetically Modified Organisms to External Organisations**

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**Introduction**

1. Applications for approval to develop genetically modified organisms (GMOs) in containment that meet the low risk criteria<sup>1</sup> can be processed by rapid assessment under sections 42 and 42A of the Hazardous Substances and New Organisms (HSNO) Act 1996, (the Act).
2. Applications for approval to import GMOs into containment that meet the low risk criteria can be processed by rapid assessment under section 42B of the HSNO Act 1996.
3. Under section 19(2)(a) of the Act, the Environmental Risk Management Authority, “the Authority” may delegate, on such terms as it thinks fit, the power to conduct such rapid assessments to any person, whether or not that person is a member of the Authority. In this context, “person” includes companies and various other organisations.
4. The Authority may also delegate the power to institutions to make minor or technical amendments, in accordance with section 67A of the HSNO Act 1996, to any approval the institution has granted, within the guidelines provided by the Authority.
5. The Authority has developed terms and conditions of delegation, and has delegated this power to certain institutions.
6. This document sets out the criteria to be used as guidelines for determining whether an organisation is appropriately qualified to be delegated this power.

**Criteria for first time applicants for delegation**

7. External delegates will be organisations - the Authority will not delegate this decision-making power to individuals.
8. The Authority’s terms of delegation stipulate requirements for an Institutional Biological Safety Committee (IBSC) and associated mechanisms. Before delegating decision-making power, the Authority must be satisfied that the organisation is prepared and able to sustain a committee with appropriate membership and adequate resources.

Note: For smaller organisations or for organisations with a narrow focus of interest, it may be necessary to appoint members who are outside of the organisation or to set up a joint IBSC with other organisations.

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<sup>1</sup> As defined in the Hazardous Substances and New Organisms (Low-Risk Modification) Regulations 2003.

9. The Authority must be satisfied that the organisation has a sufficient GMO workload to justify the maintenance of an IBSC and to sustain its members' familiarity with the approval process and criteria.

Note: The Authority will consider the number of applications expected to be handled by the institution. Projected application numbers should generally be greater than 3 per annum. Smaller organisations will be encouraged to make arrangements with an existing delegated organisation to consider applications on their behalf.

10. Character of organisation: It is expected that delegates will be academic, Crown, or commercial organisations having an active role in research involving low risk GMOs.
11. Familiarity with decision-making process and criteria: The Authority must be satisfied that the organisation possesses a thorough knowledge of the relevant parts of the HSNO Act 1996, the Regulations, the Methodology, and other policies, procedures and criteria for decision-making, and of the Authority's terms of delegation.
12. Separation of function and avoidance of conflicts of interest: The Authority must be satisfied that the organisation is able to maintain a separation of this regulatory function from business imperatives, such that the IBSC can operate in a quasi-judicial manner in accordance with statutory criteria and the terms of delegation. This includes a sufficient range of available expertise to ensure that the IBSC can operate effectively without the input of persons directly involved in the project under consideration.

Note: It would be satisfactory, or even desirable in some instances, for expertise to be provided from outside the organisation itself (in addition to the lay member who must not be associated with the institution).

13. Compliance with terms of delegation: The Authority must be satisfied that the organisation can and will comply with the terms of delegation including:
- the operation of the IBSC;
  - the proper and timely recording and reporting of decisions;
  - being subject to periodic audit by ERMA New Zealand; and
  - the payment of fees in accordance with the Authority's pricing policy.
14. Process of applying for a first-time delegation: Organisations seeking delegated powers are expected to apply in writing. Applications should meet the requirements set out in Annex B.
15. Process of renewing a delegation: Organisations seeking delegated powers are expected to reapply in writing before the current delegation expires. Applications should meet the requirements set out in Annex B.
16. The Authority may interview the proposed Chairman of the IBSC, the Biological Safety Officer, or such other persons connected with the institution to satisfy itself that the organisation includes a sufficient knowledge of the decision-making process and criteria.
17. Other documents: These criteria should be read in conjunction with "Requirements for Delegation of Power to Conduct Rapid Assessments of Applications for Development

in Containment and Importations into Containment of Low Risk Genetically Modified Organisms” (Annex B), and the instrument of delegation (Annex C).

### **Criteria for renewing delegations**

18. Once an institution has indicated that it wishes to renew its delegation it will be assessed by the Authority for eligibility against the following criteria:
- the quality and number of the decisions they have previously made;
  - the results of any audits undertaken;
  - performance against the previous delegation requirements; and
  - evidence that the organisation will continue to have a sufficient GMO workload to justify the maintenance of an IBSC and to sustain its members’ familiarity with the approval process and criteria (this may include an interview or interviews as set out in paragraph 16 above).