

## Decision Form to Import a Genetically Modified Organism into Containment by Rapid Assessment Under Section 42B

This form is a recommended decision template for use by Institutional Biological Safety Committees (IBSCs) exercising authority, delegated from the Environmental Risk Management Authority (ERMA New Zealand), to make decisions on applications to import low risk genetically modified organisms in containment.

In exercising the delegation, IBSCs are required to demonstrate that they have followed the provisions of the Hazardous Substances and New Organisms (HSNO) Act 1996, the HSNO (Low-Risk Genetic Modification) Regulations 2003 and the HSNO (Methodology) Order 1998. This form and checklist are designed to provide IBSCs with a means of recording that they have followed the processes required by the Act and the Methodology.

The checklist, therefore, serves two purposes: it provides the IBSC with a systematic approach to their deliberation, and it serves as evidence that the IBSC has met the Requirements of the Act and the Methodology. Thus it forms part of the decision.

When submitting a decision to ERMA New Zealand, the IBSC should:

1. Send an electronic copy of the decision form (Microsoft Word format) and checklist<sup>1</sup> to the following email address:

IBSC@ermanz.govt.nz

2. Post a signed copy of the completed decision form and checklist along with the application<sup>2</sup> to:

ERMA New Zealand  
PO Box 131  
Wellington  
Attention: Dr Libby Harrison  
General Manager  
New Organisms Group

3. Send a copy of the decision to the applicant.

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<sup>1</sup> For a s67A amendment, send an electronic copy of the proposal for a s67A, the new decision form (Microsoft Word format) and checklist, and *ideally* the old decision form.

<sup>2</sup> For a s67A amendment, post a signed copy of the proposal for a s67A, and the new and old decision forms and checklists.

## Institutional Biological Safety Committee Decision Form<sup>3</sup> to Import a Low-Risk Genetically Modified Organism in Containment

Amended under s67A of the HSNO Act on {DATE decision is signed}<sup>4</sup>

ERMA Office use only

Application Code:	
Application Approval Code(s):	
BCH Number(s) <sup>5</sup> :	

<b>Institutional Biological Safety Committee:</b>	<eg Massey University >
IBSC Institution Code:	<eg GMOXX/MU001 >
Application type:	To import a genetically modified organism into containment under section 40(1)(a) of the Hazardous Substances and New Organisms (HSNO) Act.>
Applicant:	< text in here>
Purpose:	<Insert purpose of application here >
Date application received:	< text in here>
Considered by:	<Members' expertise or role eg BSO, Chair, Māori community representative, Community Layperson, Microbial geneticist, Engineer, etc>
Consideration date:	< text in here>

First s67A amendment

Date application received:	< text in here>
Considered by:	<Members' expertise or role eg BSO, Chair, Māori community representative, Community Layperson, Microbial geneticist, Engineer, etc>
Consideration date:	< text in here>

Copy the above table for each subsequent amendment

### 1. Summary of the Decision:

The application to import the following organism(s) is **[approved, with controls]/[declined]** having been considered in accordance with the relevant provisions of the Hazardous Substances and New Organisms (HSNO) Act 1996, the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003, and the HSNO (Methodology) Order 1998.

<sup>3</sup> This decision form should be used in conjunction with the checklist.

<sup>4</sup> Sections highlighted in blue are to be filled in for a s67A, otherwise delete.

<sup>5</sup> Biosafety Clearing House record identification number.

The application was considered by the IBSC under delegation from the Authority as provided for under section 19(2)(a) of the HSNO Act.

## **2. Sequence of the Consideration**

In accordance with sections 42B of the HSNO Act (rapid assessment), the approach adopted by the IBSC was to identify the circumstances of the genetic modification(s), to evaluate these against the criteria set out in the HSNO (Low-Risk Genetic Modification) Regulations 2003 established under section 41 of the Act, and to consider whether there are any residual risks of significance that require further consideration (if so, see Annex A).

### 3. Organism Description Table(s)

The organism description can be specific to individual GMOs or it can be generic<sup>6</sup>. HOWEVER, the organism description needs to CLEARLY describe the full range of GMOs permitted by this approval so ERMA New Zealand can be satisfied that it conforms with the HSNO (Low-Risk Genetic Modification) Regulations 2003. For example: “not low-risk” modifications need to be clearly excluded from the vectors and donor nucleic acids if you are expressing uncharacterised nucleic acid sequences from pathogenic organisms, OR, for example, if using (non-pathogenic) *Escherichia coli* as a host, identify it as the non-pathogenic strains or strains K 12 or B.

**The organism(s) for importation are:**

<b>Name of the host organism:</b>	< text in here>
Specify the category of <b>host organism</b> e.g. <b>Category 1 or 2</b> <sup>7</sup>	< text in here>
<b>What the organism is modified with:</b>  Please specify vector and source and function of donor DNA	< text in here>
Please specify the category of genetic modification e.g. <b>Category A or B</b> <sup>8</sup>	< text in here>
Containment level e.g. PC1/PC2 <sup>9</sup>	< text in here>
Approved/Declined	< text in here>

<b>Name of the host organism</b>	
Specify the category of <b>host organism</b> e.g. <b>Category 1 or 2</b>	< text in here>
<b>What the organism is modified with:</b>  Please specify vector and source and function of donor DNA	< text in here>
Please specify the category of genetic modification e.g. <b>Category A or B</b>	< text in here>
Containment level e.g. PC1/PC2	< text in here>
Approved/Declined	< text in here>

<Copy table if more organisms>

<sup>6</sup> As described in our “Policy relating to the rapid assessment of low-risk new organisms, including medicines” (ER-PO-NO-01). For more guidance refer to ERMA New Zealand User Guide: “*Making an application for Rapid Assessment to Import into Containment Low-Risk Genetically Modified Organisms*”.

<sup>7</sup> According to the HSNO (Low-Risk Genetic Modification) Regulations 2003.

<sup>8</sup> According to the HSNO (Low-Risk Genetic Modification) Regulations 2003.

<sup>9</sup> As in the Australian/New Zealand Standard 2243.3:2002 *Safety in Laboratories: Microbiological aspects and containment facilities*.

#### 4. Use of Special Genetic Material

Human Genes or Native introduced flora and fauna:	YES	NO
Does the proposed importation include genetic material from native flora and/or fauna; or flora and/or fauna valued by Māori ?		
Does the proposed importation include human cell lines or human genetic material of Māori whakapapa or origin?		
If “YES” to either of the above please clearly record evidence that appropriate Māori consultation has occurred with local iwi regarding this approval (i.e. who was consulted, their status, and the results of the consultation).		

#### 5. Identification and Assessment of the Significant Risks and Costs of the Organism

Describe any significant (non-negligible) risks identified, along with the Committee’s assessment of the risks. Describe and justify any additional controls applied to manage the risks.

< text in here >

#### 6. Containment

Describe the containment system (physical and operational).

< text in here >

#### 7. Controls

In considering all the matters to be addressed detailed in the Third Schedule Part I “*Containment Controls for Importing, Developing or Field Testing of Genetically Modified Organisms*” of the HSNO Act, this approval is subject to the following controls:

1. The operation, management and construction of the containment facility<sup>10</sup> shall be in accordance with the **(delete where not applicable)**:
  - MAF/ERMA New Zealand Standard *Facilities for Microorganisms and Cell Cultures: 2007*<sup>11</sup>
  - MAF/ERMA New Zealand Standard *Containment Facilities for Plants: 2007*<sup>11</sup>

<sup>10</sup> Containment facility means a facility registered under section 39 of the Biosecurity Act 1993.

<sup>11</sup> Any reference to this standard in these controls refers to any subsequent version approved or endorsed by ERMA New Zealand.

- MAF/ERMA New Zealand Standard *Transitional and Containment Facilities for Invertebrates*<sup>12</sup>
- MAF/ERMA New Zealand Standard *Containment Facilities for Vertebrate Laboratory Animals*<sup>12</sup>
- The Australian/New Zealand Standard 2243.3:2002<sup>12</sup> *Safety in laboratories: Microbiological aspects and containment facilities*, at Physical Containment Level **x (PCx)**.

2. If a breach of containment occurs the facility operator must ensure that the MAF Inspector responsible for supervision of the facility has received notification of the breach within 24 hours, and shall immediately implement a contingency plan for the recovery and eradication of the organisms and viable material that has escaped.

**Additional Controls**

List any additional controls. The reasons for imposing any additional controls must be stated in Section 5 of this decision.

< text in here >

**Original signature (details typed in)**

Signed: ..... Date .....

(on behalf of the institution)

Name:

Position:

**First S67A amendment**

Amendment date (Month/year)

List how the decision was amended (eg Added “all standard and commercially available *Escherichia coli* cloning vectors” to the approved organism description).

Signed: ..... Date .....

(on behalf of the institution)

Name:

Position:

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<sup>12</sup> Any reference to this standard in these controls refers to any subsequent version approved or endorsed by ERMA New Zealand.

## Checklist

NB- this checklist should be completed by the IBSC, and signed and dated by the Chair of the IBSC and returned to ERMA New Zealand with the decision form.

- Sections referenced in the text below indicate sections of the Hazardous Substance and New Organisms Act 1996
- Clauses referenced in the text below indicate clauses of the Hazardous Substances and New Organisms (Methodology) Order 1998

		Yes/No/ N/A
<b>1</b>	<b><i>Legislative criteria for the application</i></b>	
1.1	The application was lodged pursuant to section 40(1)(a) of the Act.	
1.2	The application was considered in accordance with section 42B and matters relevant to the purpose of the Act.	
<b>2</b>	<b><i>Consideration of the application</i></b>	
2.1	The IBSC holds delegation from the Authority as provided under section 19(2)(a) of the HSNO Act.	
2.2	The purpose is provided for under section 39 of the Act.	
2.3	Does the IBSC consider the information provided by the applicant is relevant and appropriate to the scale and significance of the risks, costs, and benefits associated with the application (clause 8)?	
2.4	If NO – <please explain>	
2.5	Was any expert advice sought (clause 17)?	
2.6	If YES – name of the expert(s) and the nature of the advice sought: <text in here>	
2.7	If YES – was the applicant informed (clause 18)?	
<b>3</b>	<b><i>Assessment against the criteria for low risk genetic modifications</i></b>	
3.1	Is the IBSC satisfied that each of the genetically modified organisms described in the application meet the criteria for a low-risk genetic modification specified in the criteria made under section 41 of the Act, being the HSNO (Low-Risk Genetic Modification) Regulations 2003?  <If not, give details>	

<b>4</b>	<b><i>Applications involving native flora and fauna</i></b>	
4.1	Does the application involve native or valued introduced flora and/or fauna as host organisms or as a source of genetic material? (Please ensure section 4 of decision form is complete.)	
<b>4</b>	<b><i>Applications involving human genetic material or human cells</i></b>	
4.2	Does the application use any genetic material or cells obtained directly from human beings?	
4.3	If YES, has approval from an Ethics Committee been obtained?	
4.4	Does the application involve the use of human cells or human genetic material sourced directly from individuals of Māori whakapapa or origin?	
4.5	If YES, please record details in Section 4 of the decision (who was consulted, their status and the results of the consultation).	
<b>5</b>	<b><i>Identification of significant risks<sup>13</sup></i></b>	
5.1	Are there any significant risks or costs to the environment, including the sustainability of all native and valued introduced flora and fauna?	
5.2	Are there any significant risks to the intrinsic value of ecosystems?	
5.3	Are there any significant risks or costs to human health, including public health?	
5.4	Are there any significant risks to Māori and their taonga?	
5.5	Are there any significant economic risks or costs?	
5.6	Are there any risks to New Zealand's international obligations, including DNA derived from CITES species or use of CITES species as host organisms?	
	If YES is checked in any of 5.1-5.6, please list the significant risks identified in section 5 of the decision form and discuss how they were assessed in terms of likelihood and consequence, and what controls were imposed to manage them <sup>14</sup> .	

<sup>13</sup> See Annex A

<sup>14</sup> Clauses 12 and 13 of the Methodology.

<b>6</b>	<b><i>Containment of the organisms</i></b>	
6.1	Has the IBSC considered the adequacy of containment in accordance with section 42B(2)?  Please record details in sections 6 and 7 of the decision. Please ensure the containment controls have been specified. Note that controls relevant to the physical containment level set in the Regulations cannot be removed.	
6.2	Are any additional measures proposed because of the particular nature of the organism(s)? If YES, please ensure additional controls are listed on the decision form.	
6.3	Are there any other matters that may affect the adequacy of containment such as the expected time-frame for the project, and external matters such as the potential for sabotage? If YES, please explain.	
<b>7</b>	<b><i>Decision</i></b>  In this section YES confirms approval – if any of the answers to 7.1-7.4 are NO, then the application is declined.	
7.1	The IBSC is satisfied that the application is for one of the purposes specified in section 39 of the Act.	
7.2	Based on analysis of the information provided, and having considered the characteristics of the organisms and the modifications and the criteria for low-risk genetic modification detailed in the HSNO (Low-Risk Genetic Modification) Regulations 2003, it is the view of the IBSC that the organism(s) meet the criteria for rapid assessment (as per section 42B(2)).	
7.3	The IBSC is satisfied that the proposed containment regime together with any additional controls imposed will adequately contain the organism(s) as required by section 42B(2) of the Act.	
7.4	In accordance with clause 36(2)(b) of the Methodology the IBSC records that, in reaching this conclusion, it has applied the relevant criteria from the Methodology.	
7.5	The application for importation of a genetically modified organism (detailed) is thus [approved]/[declined], with controls as detailed on the decision document.	

Original details typed in

Signed: .....

Date .....

(on behalf of the institution)

Name:

Position:

## **Annex A - Guidelines for Dealing With Significant Risks**

Significant risks are those risks that the IBSC considers are not negligible (i.e. they require active management beyond the normal requirements of the specified physical containment level). In most circumstances the default controls will be adequate to contain the organism(s), and there will not be any significant residual risks. However, there may be some instances where the IBSC considers that this is not the case and where additional controls should be applied. In these situations the IBSC may choose to present a full assessment of the significant residual risk or contact ERMA New Zealand.

Where the IBSC considers that there are significant risks that require full consideration, then they may decide to use the following approach to assessing these risks, prior to evaluating options for managing or reducing the risks.

If the IBSC deems that the organism(s) cannot be adequately contained or that the risks cannot be reduced to a negligible level by applying additional controls, then the application is not appropriate for rapid assessment and should be declined or referred to ERMA New Zealand.

### **Assessment of the Significant Adverse Effects (Risks and Costs) of the Organism(s)**

Adverse effects (risks and costs) may be grouped into categories reflecting those used in the identification section of the decision e.g., effects on, for example:

- biological and physical environment
- human welfare including health and safety
- social or community conditions
- Māori issues and concerns, and
- economic aspects.

Each adverse effect should be discussed under a separate heading and cross-referenced to the identification section of the decision. Information provided that has been produced for other processes or jurisdictions (in New Zealand or overseas) should be discussed with reference to clause 20.

### **Example**

Outline of the application: The applicant is proposing to import a transgenic plant where the plant will be allowed to form full shoots and roots, and the pollen will be required for scientific analysis. (For this example and simplicity only one risk has been identified, often there will be more than one significant risk).

The following wording provides an example for the Identification and Assessment section of the decision form.

*The risks and costs assessed were those identified as potentially significant, having regard for those matters set out in clauses 9 and 10 of the Methodology. Risks were considered in terms of the requirements of clause 12 of the Methodology, including especially the assessment of consequences and probabilities, the impact of uncertainty and the impact of risk management. Costs were considered in terms of clause 13 of the Methodology.*

When going through the checklist, section 4.1 was checked as YES because the IBSC identified a significant risk that the genetically modified organism may cause an adverse effect on the environment if the pollen escaped from containment and was found to hybridise with flora.

The IBSC proceeded to address this significant risk by the following process.

*Significant risks, costs and benefits identified for assessment and evaluation were as follows, following clauses 9 and 10 of the Methodology, which incorporate sections 5, 6, and 8 of the HSNO Act. The components of this risk are:*

- *the likelihood of escape from containment*
- *the likelihood of hybridisation with valued plant species*
- *the effect should hybridisation occur*

*The Committee considered the nature of the potential adverse effect (clause 12(a)), relating to <plant species> hybridising with other <plant species> if they escaped from containment.*

*The Committee was unable to determine whether hybrids occur between <plant species>, so there is uncertainty over whether hybrids with the naturalised species could occur (clause 12(e)). Since <plant species> already in New Zealand are recorded as uncommon, the Committee considers that it is very unlikely for escaping pollen to land on receptive flowers outside of containment but the effect if it should occur would be minor-moderate, therefore the risk is low (clause 12(b)).*

*In order to reduce the risk, by reducing the likelihood of escape of pollen, the Committee has proposed an additional control. In the event of initiating flowering, all pollen shall be contained by bagging and seed shall be collected. The containment manual shall be updated to reflect the process for bagging pollen and collecting seed.*

*The Committee is satisfied that the <plant species> are easily identifiable due to their phenotype, and easily eradicated (clause 12(d)). Eradication procedures include physical removal for small scale infestations or by a range of common soil-applied and plant applied herbicides including Glyphosphate, Diuron, Metribuzin, Simazine, Chlorpropham, DCPA and Trifluralin for larger scale infestations.*

*The Committee considers that the risk of hybridisation is reduced to negligible by the additional controls on pollen and seed. (clause 12(c)).*