Institutional Biological Safety Committee decision form[1]

Institutional Biological Safety Committee:	Massey University
IBSC Institution Code:	GMO 03/MU/20 GMD002749
Application category:	To develop in containment a genetically modified organism under section 40(1)(b) of the Hazardous Substances and New Organisms (HSNO) Act
Purpose:	To develop expression vectors with self-cleaving solubility fusion tags
Applicant:	Massey University
Date application received by IBSC:	11 July 2003
Considered by what members:	:x
Date of consideration:	11 July 2003

1 Summary of the decision:

The application to develop the following organism(s) is **approved** with controls, having been considered in accordance with the relevant provisions of the Hazardous Substances and New Organisms (HSNO) Act 1996, the Hazardous Substances New Organisms (Low Risk Regulations) 1998, and the HSNO (Methodology) Order 1998.

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

The organism(s) **approved** are:

Name of the organism:	**What the organism is modified with:**	**Development of the organism involves an approved Schedule 2 host/vector system as in HSNO Regulations. Category requirements are (please specify details of category eg B(b)(i)) -**	**Containment level as in the Australian/New Zealand Standard AS/NZS 2243.3 2002 Safety in Laboratories Part 3: Microbiological aspects and containment facilities eg PC1/PC2**
1. *Escherichia coli* strain DH5ά	1. Vectors pTYB1, pTYB2, pTYB3, pTYB4, pTYB11, pTYB12 (NEB); DNA coding for *E.coli* NusA protein, thioredoxin or maltose-binding protein	1. B (a) (i) & B (b) (iv) (A)	1. PC2
2. *Escherichia coli* strain XL-1 Blue and TOP10F'	2. Vectors pTYB1, pTYB2, pTYB3, pTYB4, pTYB11, pTYB12 (NEB); DNA coding for *E.coli* NusA protein, thioredoxin or maltose-binding protein	2. B (a) (ii) & B (b) (iv) (A)	2. PC2

[1] This decision form should be used in conjunction with the checklist

Human Genes:	YES	NO
Does the proposed development involve human genes?		✓
If **YES** - is the genetic material derived directly from humans?		
If **YES** – is the genetic material derived indirectly from humans ie commercial source?		
If genetic material is derived directly from humans, was ethics committee approval obtained?		
If **YES** – what was the name of the committee, and the date of the approval?		
If **NO** – indicate why not		
Native flora and fauna (section 6d & 8 of the HSNO Act):	**YES**	**NO**
Does the proposed development use genetic material from native flora and/or fauna?		✓
Does the proposed development use native flora and fauna as host organisms?		✓
If DNA from native flora and fauna is involved, was consultation with Maori carried out?		
If **YES** - provide details of consultation		
If **NO** – indicate why not and what steps were taken instead.		

2 Containment

Describe the containment system (physical and operational).

MAF-approved PC2 laboratory (in accordance with MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02 "Containment Facilities for Micro-organisms").

3 Identification of the significant risks and costs of the organism

In accordance with section 42 of the 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 specified in section 41, and to consider whether there are any residual risks of significance that require further consideration. Refer to Annex A for guidance on identifying and assessing significant risks and costs.

No significant risks or costs were identified.

4 Controls

In considering all the matters to be addressed detailed in the Third Schedule Part I Containment Controls for Development and Field Testing of Genetically Modified Organisms of the HSNO Act, the IBSC approval of the organism(s) is subject to the following controls:

1) The operation, management and construction of the facility shall be in accordance with the:

   a) The MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02 "Containment Facilities for Micro-organisms".

b) Australian/New Zealand Standard (AS/NZS) 2243.3:2002 Safety in Laboratories: Part 3: Microbiological aspects and containment facilities, at Physical Containment Level 2 (PC2).

2) The facility shall be approved and registered by MAF Biosecurity Authority as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02.

3) All culture products and associated materials shall be autoclaved or incinerated before being disposed of.

4) If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.

5) The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

5 Additional controls

List any additional controls.

No additional controls.

Sig ..... 24.7.03 Date

Nar

Position: I/ Chairperson, Massey University IBSC

Send a copy of the decision form, the checklist and the application to:

- ERMA New Zealand, PO Box 131, Wellington
  Attention: M[redacted]

Send a copy of the decision form to:

- Applicant

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

		Yes	No	N/A
1	**Legislative criteria for the application**			
1.1	The application was lodged pursuant to section 40(1)(b) of the HSNO Act. The decision was determined in accordance with section 42 (rapid assessment) and matters relevant to the purpose of the Act, as specified under Part II of the HSNO Act	✓		
1.2	Consideration of the application followed the relevant provisions of the Hazardous Substances and New Organisms (Methodology) Order 1998 (the Methodology). Unless otherwise stated, references to clauses in this decision refer to clauses of the Methodology.	✓		
1.3	Was any expert advice sought under clause 17?		✓	
1.5	If **YES** – name of the expert			
1.6	If **YES** – was the applicant informed under clause 18?			
2	**Consideration of the application**			
2.1	The IBSC holds delegation from the Authority as provided under section 19 of the HSNO Act.	✓		
2.2	The purpose is appropriate under section 39(1)(a) of the Act: The development of any genetically modified organism.	✓		
2.3	Does the IBSC consider the information provided by the applicant relevant and appropriate to the scale and significance of the risks, costs, and benefits associated with the application (as required by clause 8 of the Methodology)?	✓		
2.4	If **NO** – discuss			
3	**Sequence of the consideration**			
3.1	In accordance with section 42 of the Act (rapid assessment), the approach adopted by the IBSC was to identify the circumstances of the genetic modification(s), to evaluate these against the Regulations established under section 41 of the Act, and to consider whether there are any residual risks of significance that require further consideration.	✓		
4	**Identification of significant risks**			
	NB Since applications that are considered under section 42 do not require balancing of adverse and beneficial effects, this section concentrates on identifying significant risks and costs as a basis for ensuring the adequacy of the proposed controls. *The relevant risks are those specified in clauses 9-10, and reference should be made to the relevant clauses. 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 cases where the IBSC considers that this is not the case and where additional controls should be applied. In this case the IBSC may choose to present a full assessment of the significant residual risks. Annex A provides a suggested format for this.*			
4.1	Are there any significant risks or costs to the environment?		✓	
4.2	Are there any significant risks or costs to human health?		✓	
4.4	Are there any significant risks to Maori and their taonga?		✓	

		Yes	No	N/A
4.5	Are there any significant economic risks or costs?		✓	
4.6	If the organism(s) were to escape from containment, would they be able to establish an undesirable self-sustaining population in NZ?		✓	
4.7	Would the organism(s) be easily eradicated if an undesirable self-sustaining population established?			✓
	If YES is checked in any of 4.1-4.6, or if NO is checked for 4.7, please list the risks identified on the decision form and discuss how they were assessed in terms of likelihood and consequence, and what controls were imposed to manage them. Refer to clauses 12 and 13.			
5	**Applications involving native flora and fauna**			
5.1	Does the application use genetic material from native flora and/or fauna?		✓	
5.2	Does the application use native flora and fauna as host organisms?		✓	
5.3	In accordance with section 8 of the Act, was consultation with Maori carried out?			✓
	If **YES**, please provide a discussion below about who was consulted, their status and the results of the consultation.			
6	**Applications involving human DNA**			
6.1	Does the application use genetic material obtained indirectly from human beings? (ie from a genebank)		✓	
6.2	Does the application use genetic material obtained directly from human beings?		✓	
6.3	If **YES** is answered to 6.2 - has approval from an Ethics Committee been obtained?			
7	**Assessment against the criteria for low risk genetic modifications**			
7.1	Does the IBSC consider that the development of **each** of the genetically modified organisms described in the application meet the criteria for a low-risk genetic modification specified in the regulations made under section 41 of the Act, being the HSNO (Low Risk Genetic Modification) Regulations 1998?	✓		
8	**Containment of the organisms**			
8.1	In carrying out its consideration, did the IBSC consider the adequacy of containment in accordance with section 42(2) and the magnitude and probability of the potential adverse effects (risks and costs?). *NB The IBSC should include details of the modifications and state which Category of the low risk regulations that they fall within.* *The IBSC should also specify the level of containment relevant to that category (the controls relevant to the level of containment are detailed at the end of the decision form). Note that the IBSC may add additional controls where I considers these are necessary to ensure containment, but that controls relevant to the physical containment level set in the Regulations cannot be removed.*	✓		
8.2	Will the containment facility be operated and constructed in accordance with the: (a) the Australian/New Zealand Standard AS/NZS 2243.3:2002 Safety in Laboratories: Part 3: Microbiological aspects and containment facilities at Physical Containment Level 2 (PC2); and (b) the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02.	✓		
8.3	Are any additional measures proposed because of the particular nature of the organism(s) or the proposed procedures?		✓	
	If **YES**, these are: [Additional controls should be also listed on the decision form]			

		Yes	No	N/A
8.5	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 discuss			
9	**Decision** In this section **YES** confirms approval – if any of the answers to 9.1-9.4 are **NO**, then the application is declined.			
9.1	The IBSC is satisfied that pursuant to section 45(1)(a)(i) of the Act, this application is for one of the purposes specified in section 39(1) of the Act, being section 39(1)(a): The development of any genetically modified organism?	✓		
9.2	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 1998, it is the view of the IBSC that the organism(s) meet the criteria for rapid assessment (as per section 42(2)).	✓		
9.3	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 42(2) of the Act?	✓		
9.4	In accordance with clause 36(b) of the Methodology the IBSC records that, in reaching this conclusion, it has applied the following criteria from the Methodology: Where relevant briefly discuss relevant clauses of the Methodology • clause 9 - • clause 10 – minimum standards criteria (sections 36 and 37) • clause 12 – evaluation of assessment of risks (to meet requirements of section 41) • clause 21 – the decision accords with the requirements of the Act and regulations	✓		
9.5	The application for development of a genetically modified organism (detailed) is thus **approved**, with controls as detailed on the decision document.	✓		

24·7·03

{DATE}

Massey University IBSC