Rec'd 23/12/04

ENTERED - 1 FEB 2005

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GMD 05012

Institutional Biological Safety Committee decision form to develop genetically modified organisms in containment[1]

Institutional Biological Safety Committee:	University of Auckland Biological Safety Committee
IBSC Institution Code:	GMO04-UA0031
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 investigate the potential of hGH and OXA1 to initiate neoplasia: One Step Oncogenisis
Applicant:	The University of Auckland
Date application received by IBSC:	7 December 2004
Considered by what members:	A quorate committee
Date of consideration:	7 December 2004. Amendments approved 16 December 2004.

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 and New Organisms (Low-Risk Genetic Modification Regulations) 2003, and the HSNO (Methodology) Order 1998.

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

The organism(s) for development **genetic modification** are:

Name of organism(s):	*Escherichia coli* (non pathogenic, laboratory adapted strains) *Saccharomyces cerevisiae*, *Pichia pastoris* Mammalian cell lines (derived from *Homo sapiens, Mus musculus, Mus spretus, Rattus norvegicus, Rattus rattus, Cricetus cricetus, Cricetulus griseus, Canis familiaris, Cavia porcellus, Mesocricetus auratus, Oryctolagus cuniculus and Cercopithecus aethiops*) Insect cell lines (derived from *Drosophila melanogatser, Trichoplusia ni and Spodoptera frugiperda*) gaster
Category of host organism, e.g. Category 1 or 2:	Category 1 (as per R7 of the HSNO (Low Risk Genetic Modification) Regulations, 2003
What the organism is modified with. Specify vector and donor DNA	Non self-transmissible cloning and expression vectors with human growth hormone (hGH), and with commercially available genes from *Homo sapiens, Mus*

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

	norvegicus encoding: HOXA1 Cell adhesion receptors Cell membrane proteins Cell surface signalling proteins Signalling molecules associated with cell surface molecules, Signal transduction molecules Anti-apoptotic proteins Transcription factor proteins Transcriptional and promoter elements associated with the above genes cDNA sequences encoding fusion, reporter and tagging constructs Provided genes will not encode toxins with an LD50 less than 100 ug/kg
Specify the category of genetic modification, e.g. Category A or B	Category A (as per R5 of the HSNO (Low Risk Genetic Modification) Regulations, 2003
Containment level, e.g. PC1/PC2	PC1

Please note: the organism description can be specific to individual GMOs or it can encompass a project description[2]. HOWEVER, the organism description needs to CLEARLY delineate the boundaries 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 using uncharacterised nucleic acid sequences from pathogenic organisms OR, for example, if using *Escherichia coli* as a host, specify it is the non-pathogenic strains or strains K 12 or B.

Human Genes or Native flora and fauna:	YES	NO
~~Does the proposed development use genetic material from native flora and/or fauna?~~		X
Does the proposed development involve human genes?	X	
PLEASE MAKE SURE YOU COMPLETE SECTIONS 5 AND 6 OF THE CHECKLIST AND PROVIDE EVIDENCE OF ANY CONSULTATION OR ETHICS COMMITTEE APPROVAL		

2 Containment

Describe the containment system (physical and operational) **PC1**.

[2] As described in our "Policy relating to the rapid assessment of low-risk new organisms, including medicines" (ER-PO-01-2) or for more guidance refer to "ERMA New Zealand User Guide to making an application for approval to import into containment low risk genetically modified organisms under section 40 of the Hazardous Substances and New Organisms Act 1996".

3 Identification of the significant risks and costs of the organism

In accordance with section 42 and 42A of the Act (rapid assessment), the approach adopted by the IBSC was to identify the type and 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.

4 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, 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:

   a) The MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02 PC1, and

   b) The Australian/New Zealand Standard (AS/NZS) 2243.3:2002 Safety in Laboratories: Part 3: Microbiological aspects and containment facilities, as amended by MAF/ERMA standard, 154.03.02.

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 approved organism 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: -

1. All work involving culture of human or animal cells must be carried out in a Class 2 Hood unless the origin and properties of the cells are sufficiently characterised and are known not to contain infectious agents.
2. The Biological Safety Officer will be notified of any accident or incident involving GMOs.
3. The Principle Investigator in charge of this project has the responsibility to ensure work practices in the laboratory meet AS/NZS 2243.3: 2003 "Safety in the Laboratory: Microbiology".
4. Transfections to be performed in a Class 2 Biohazard cabinet.
5. Gloves to be worn while performing transfections.
6. Cells derived from investigators or lab personnel must not be used for transfections/transformations.

Signed: ..... 17th December 2004 Date

Name:

Position: Chairman, The University of Auckland Biological Safety Committee

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 and 42A (rapid assessment) and matters relevant to the purpose of the Act, as specified under Part II of the HSNO Act	X		
1.2	Consideration of the application followed the relevant provisions of the Hazardous Substances and New Organisms (Methodology) Order 1998 (the Methodology).	X		
1.3	Was any expert advice sought under clause 17?		X	
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(2)(a) of the HSNO Act.	Y		
2.2	The purpose is appropriate under section 39(1)(a) of the Act: *The development of any genetically modified organism.*	Y		
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)?	Y		
2.4	If **NO** – discuss			
3	**Sequence of the consideration**			
3.1	In accordance with sections 42 and 42A 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.	Y		
4	**Identification of significant risks**			
4.1	Are there any significant risks or costs to the environment?		X	
4.2	Are there any significant risks or costs to human health?		X	
4.4	Are there any significant risks to Maori and their taonga?		X	
4.5	Are there any significant economic risks or costs?		X	
4.6	Are their any risks to New Zealand's international obligations, including DNA derived from CITES species or use of CITES species as host organisms?		X	
	If YES is checked in any of 4.1-4.6, please list the risks identified on the decision form and discuss how they were assessed in terms			

		Yes	No	N/A
	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?		X	
5.2	Does the application use native flora and/or fauna as host organisms?		X	
5.3	In accordance with section 8 of the Act, was consultation with Maori carried out?	Y		
	If **YES**, please provide a discussion below about who was consulted, their status and the results of the consultation. [redacted]gati Whatua Maori representative.			
6	**Applications involving human DNA**			
6.1	Does the application use any genetic material or cell lines obtained either directly or indirectly from human beings?	Y		
6.2	If **YES** is answered to 6.1 - has approval from an Ethics Committee been obtained for any DNA sourced directly from human beings? DNA will be obtained from generic sources only.			X
6.3	If **YES**, please provide a discussion below about who was consulted, their status and the results of the consultation. [redacted]Ngati Whatua Maori representative.	Y		
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 2003?	Y		
8	**Containment of the organisms**			
8.1	In carrying out its consideration did the IBSC considered the adequacy of containment in accordance with section 42(2) *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 it considers these are necessary to ensure containment, but that controls relevant to the physical containment level set in the Regulations cannot be removed.*~~	Y		
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 *specify* (PC1) as amended by MAF Biosecurity Authority/ERMA ERMA New Zealand Standard 154.03.02. (b) the MAF Biosecurity Authority/ERMA ERMA New Zealand Standard 154.03.02.	Y		
8.3	Are any additional measures proposed because of the particular nature of the organism(s) or the proposed procedures?	Y		

		Yes	No	N/A
	If **YES**, these are: [Additional controls should be also listed on the decision form] 1. All work involving culture of human or animal cells must be carried out in a Class 2 Hood unless the origin and properties of the cells are sufficiently characterised and are known not to contain infectious agents. 2. The Biological Safety Officer will be notified of any accident or incident involving GMOs. 3. The Principle Investigator in charge of this project has the responsibility to ensure work practices in the laboratory meet AS/NZS 2243.3: 2003 "Safety in the Laboratory: Microbiology". 4. Transfections to be performed in a Class 2 Biohazard cabinet. 5. Gloves to be worn while performing transfections. 6. Cells derived from investigators or lab personnel must not be used for transfections/transformations.			
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?		N	
	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 the 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*?	Y		
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 2003, it is the view of the IBSC that the organism(s) meet the criteria for rapid assessment (as per section 42(2)).	Y		
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?	Y		
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 and 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	Y		
9.5	The application for development of a genetically modified organism (detailed) is thus **approved**, with controls as detailed on the decision document.	Y		

{SIGNATURE}

{Date} 17th December, 2004.

The University of Auckland Biological Safety Committee