Institutional Biological Safety Committee decision form[1] to import a low-risk genetically modified organism in containment

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Application Code:	GMC07006
Application Approval Code(s):	GMC001315
BCH Number[2] (if applicable):	38218

Institutional Biological Safety Committee:	Massey University
IBSC Institution Code:	GMO07/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:	Massey University
Purpose:	To import genetically modified Chinese Hamster Ovary (CHO) cells that have the appropriate gene integrated into their genome to overexpress the recombinant protein, myostatin, for biochemical and structural analysis
Date application received:	2 March 2007
Considered by:	Chairperson, BSO, Biochemist/Molecular Biologist, Ecologist/ Environmental Scientist, Molecular Immunologist, Lay Member, Maori Member, Maori Advisor (2), Engineer
Consideration date:	2 March 2007

1. Summary of the decision

The application to import 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.

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).

[1] This decision form should be used in conjunction with the checklist.
[2] Biosafety Clearing House record identification number.

3. Organism description table(s)

The organism description can be specific to individual GMOs or it can be generic[3]. 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:

Name of the host organism:	*Cricetulus griseus* (Chinese Hamster) ovary cell lines (Milne-Edwards 1857)
Specify the category of **host organism** **e.g. Category 1 or 2**[4]	Category 1
What the organism is modified with: Please specify vector and donor DNA	pMXSND expression vectors containing *Mus musculus* or *Homo sapiens* myostatin cDNA stably incorporated into the genome of Chinese hamster ovary cell lines
Please specify the category of genetic modification e.g. **Category A or B**[5]	Category A
Containment level e.g. PC1/PC2[6]	PC1
Approved/declined	Approved

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).		

[3] As described in our "Policy relating to the rapid assessment of low-risk new organisms, including medicines" (ER-PO-01-2). 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".*

[4] According to the HSNO (Low-Risk Genetic Modification) Regulations 2003.

[5] According to the HSNO (Low-Risk Genetic Modification) Regulations 2003.

[6] As in the Australian/New Zealand Standard 2243.3:2002 with modifications referred to in the MAF Biosecurity Authority ERMA NZ Containment Standards.

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.

No significant risks or costs were identified.

6. Containment

Describe the containment system (physical and operational).

The minimum level required is PC1 for *Cricetulus griseus* (in accordance with MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02, "Containment Facilities for Micro-organisms").

The work will take place in a MAF-approved PC2 laboratory.

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[7] shall be in accordance with the:
   - The MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02, "Containment Facilities for Micro-organisms"; and
   - The Australian/New Zealand Standard 2243.3:2002, "Safety in Laboratories: Microbiological Aspects and Containment Facilities", at Physical Containment Level 1 (PC1).
2. 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.
3. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

Additional controls

List any additional controls

No additional controls.

[7] Containment facility means a facility registered under section 39 of the Biosecurity Act 1993

Signed: ..... Date .....
(on behalf of the institution)

Name:

Position: Chairperson, Massey University IBSC

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
1	***Legislative criteria for the application***	
1.1	The application was lodged pursuant to section 40(1)(a) of the Act.	Yes
1.2	The application was considered in accordance with section 42B and matters relevant to the purpose of the Act.	Yes
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.	Yes
2.2	The purpose is provided for under section 39 of the Act.	Yes
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)?	Yes
2.4	If NO – <please explain>	
2.5	Was any expert advice sought (clause 17)?	No
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)?	
3	***Assessment against the criteria for low risk genetic modifications***	
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>	Yes

4	***Applications involving native flora and fauna***	
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.)	No
4	***Applications involving human genetic material or human cells***	
4.2	Does the application use any genetic material or cells obtained directly from human beings?	No
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?	No
4.5	If YES, please record details in section 4 of the decision (who was consulted, their status and the results of the consultation).	
5	***Identification of significant risks***[8]	
5.1	Are there any significant risks or costs to the environment, including the sustainability of all native and valued introduced flora and fauna?	No
5.2	Are there any significant risks to the intrinsic value of ecosystems?	No
5.3	Are there any significant risks or costs to human health, including public health?	No
5.4	Are there any significant risks to Māori and their taonga?	No
5.5	Are there any significant economic risks or costs?	No
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?	No
	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[9].	

[8] See Annex A
[9] Clauses 12 and 13 of the Methodology.

6	***Containment of the organisms***	
6.1	Has the IBSC considered the adequacy of containment in accordance with section 42B(2)? Please record details in section 6 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.	Yes
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.	No
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.	No
7	***Decision*** 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.	Yes
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)).	Yes
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.	Yes
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.	Yes
7.5	The application for importation of a genetically modified organism (detailed) is thus approved, with controls as detailed on the decision document.	Yes

Signed: ..... Date .....
(on behalf of the institution)

Name:

Position: Chairperson, Massey University IBSC