Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

Application for the Certification of a Physical Containment Facility

Applicant organisation name:	

Is this application accompanied by an application for a declaration that certain information be treated as **Confidential Commercial Information (CCI)**?

Yes		**No**	

Time taken to complete this form:

Hours	Minutes

General Instructions

Application for certification

This application is for the certification of a facility to a specified containment level in accordance with Guidelines for the Certification of Physical Containment Facilities issued under the *Gene Technology Act 2000* (Commonwealth) (the Act) and, as applicable, corresponding state legislation.

The Gene Technology Regulator (the Regulator) needs the information you provide in this form to assist in determining whether to certify the facility. If the information you provide is incorrect or incomplete the Regulator's decision about this application may be delayed or may result in the Regulator not granting the certification. The Regulator may require you to provide additional information. If this is necessary, you will be notified of the additional information required.

If the Regulator certifies the facility, the certification holder will be obliged to ensure the facility complies with the conditions of the certification.

Accuracy of information

The information you provide in this application must be true and accurate. The Act (and corresponding state law) provides for imprisonment and fines where a person gives information to the Regulator that the person knows to be false or misleading.

All sections, parts and questions must be completed unless otherwise directed on the form. If the spaces provided are not sufficient to set out the requested information, you should attach additional information and clearly mark on the attachment which section, part and question the information relates to. You should also indicate against the item that there is additional information attached, noting the attachment title/number and the page number(s).

Timeframes

Under Regulation 14(1)(a) of the *Gene Technology Regulations 2001,* the Regulator must consider and decide on an application for certification within 90 working days after the day the application is received by the Regulator. However, days on which the decision-making process cannot proceed because the Regulator is waiting for information that the applicant has been asked to provide under section 85, do not count as part of this timeframe.

Confidentiality

If you wish to make an application for a declaration that specifies information that is Confidential Commercial Information (CCI) for the purposes of the *Gene Technology Act 2000* and corresponding state law, you must complete a CCI application form and forward it together with this application.

Ethics

The National Framework of Ethical Principles in Gene Technology 2012 (Ethics Framework) has been developed by GTECCC to provide a national reference point for promoting ethical conduct in gene technology. The Ethics Framework is available on the OGTR website.

Personal Information

Personal information is collected by the OGTR to enable the Gene Technology Regulator to perform the functions set out under the Act. Personal information specified in this form is collected for the purpose of assessing applications under the Act and is handled in accordance with the Australian Privacy Principles set out in the *Privacy Act 1988*. More information can be accessed at the OGTRs Privacy and personal information web page. The OGTRs privacy policy explains how the OGTR collects, stores, uses, and discloses personal information, including how a person may seek access to, or correct their personal information, and how a complaint about a breach of the Australian Privacy Principles can be made.

Authorisation

If submitting the application by post or fax, Section 4 ('Declarations' page) must be signed by a person authorised to sign on behalf of the organisation. If you are sending the application by e-mail, please either:

- attach a scanned image of Section 4, or
- if you are the person who is authorised to sign the application, include a statement in your e-mail stating that you are a person duly authorised to sign the request.

Further information

- Further information is available on the OGTR website www.ogtr.gov.au.
- The OGTR can be contacted by telephone on 1800 181 030 or e-mail at ogtr@health.gov.au

Lodging the application

The completed application form can be lodged with the OGTR:

- **Online** at the OGTR website which is our preferred method.
- **By mail** to the Office of The Gene Technology Regulator, MDP 54, GPO Box 9848, CANBERRA, ACT, 2601; or
- **By e-mail** to ogtr.applications@health.gov.au or
- **By fax** to the Office of The Gene Technology Regulator on (02) 6271 4202; or
- **In person** at Scarborough House, Atlantic Street, Woden Town Centre, ACT, 2606

You are encouraged to retain a copy of the completed application for your records.

Acknowledgement of receipt

We will acknowledge receipt of the application by email and assign it an OGTR reference number. Please cite this reference number whenever you contact us regarding the application. If you have not received any communication acknowledging the receipt of your application within two weeks of submission, please e-mail ogtr.applications@health.gov.au or telephone 1800 181 030.

Section 1
Contact Information for Application and Facility

Question 1

Application contact. Please provide contact details for the person whom an OGTR evaluator can contact regarding queries about this application. The certification instrument and facility door signs will be sent to this person if the application is approved.

Personal title, eg Ms/Mr/Dr:	Enter title
Surname:	Enter name
First name:	Enter first name
Preferred first name if different:	Enter first name
Phone number:	Enter phone number
Mobile number:	Enter mobile number
Email address:	Enter email address
Job title:	Enter job title
Organisation:	Enter organisation
Street number and name:	Enter street number and name
Town/city/locality:	Enter town/city
State/territory:	Enter state/territory
Postcode:	Enter postcode
Country:	Enter country
Postal address, if different:	Enter postal address

Question 2

Facility contact (This is a person, such as a facility manager, that the OGTR can contact for further information about the facility during the evaluation of this application.)

Personal title, eg Ms/Mr/Dr:	Enter title
Surname:	Enter surname
First name:	Enter first name
Preferred first name, if different:	Enter preferred first name
Phone number:	Enter phone number
Mobile number:	Enter mobile number
Email address:	Enter email address
Job title:	Enter job title
Organisation:	Enter organisation
Street number and name:	Enter street number and name
Town/city/locality:	Enter town/city
State/territory:	Enter state/territory
Postcode:	Enter postcode
Country:	Enter country
Postal address, if different:	Enter postal address
Relevant qualifications and skills:	Enter relevant qualifications and skills

Section 2
Facility Details

Question 3

Level and type of containment facility

Please indicate the physical containment (PC) level and facility type on the list below.

Guidance on the OGTR's PC levels and facility types is provided in the *Guide to Physical Containment Levels and Facility Types* available on the OGTR website, as part of the explanatory information accompanying the guidelines for certification of physical containment facilities. You are welcome to contact the OGTR if you wish to clarify your choice of PC level / facility type.

- ☐ PC1 Facility

- ☐ PC2 Animal Facility
- ☐ PC2 Aquatic Facility
- ☐ PC2 Constant Temperature Room
- ☐ PC2 Invertebrate Facility
- ☐ PC2 Laboratory
- ☐ PC2 Large Scale Facility
- ☐ PC2 Large Grazing Animal Facility
- ☐ PC2 Plant Facility

- ☐ PC3 Facility

- ☐ PC4 Facility

If selected PC2 Animal Facility/PC2 Plant Facility/PC2 invertebrate Facility, please indicate responses to the following questions:

Type of animals or plants or invertebrate used in the facility	
Whether work will involve introduction of a GM microorganism into a plant or animal or invertebrate	
If yes, provide details for the type of enclosure used to house these animals, plants or invertebrates.	

Question 4

OGTR certification

Is any part of this facility currently certified by the Regulator under an existing certification (*e.g.* is the certification held or used by another organisation? is the area covered by another certification?)

Yes		No		Unknown	

If YES, please indicate the OGTR certification number, PC level and facility type.

OGTR certification number:	
PC level & facility type: (e.g. PC2 Laboratory)	

Question 5

Facility ownership

Does the applicant organisation own the facility?

Yes		No	

If NO, can the applicant organisation comply with certification conditions which require:

(a) upkeep of the physical containment attributes of the facility;
(b) maintenance and testing of fittings required by the conditions of certification; and
(c) the capacity to exclude persons from the facility?

Yes		No	

Please attach a letter from the owner of the facility agreeing to the certification of the facility by the applicant.

Question 6

Facility equipment

Does the applicant organisation own the equipment in the facility?

Yes		No	

If NO, can the applicant organisation comply with any conditions which require testing, maintenance, and operation of the containment equipment?

Yes		No	

Question 7

Facility name and address details

Please provide the facility details below. This information is required to assist the OGTR to identify and locate the facility. The standard format for the OGTR name will match the following format, which generally starts from the smallest identifiable component and ends with the largest:

> Room number(s); Floor/Level; Building name/number; then any additional description of the facility which assists in the identification of location e.g. University Campus, Research Institute etc.
>
> Example:
> Rooms 102 to 110, Level 1, George Hamblin Building (#25), University of Manangatang.

Room number(s):			
Floor/Level:			
Building name/number:			
Additional description (if any)			
Street number and name:			
Locality: (City/Suburb/Location)		State:	
Postcode			

Question 8

Anteroom / Airlock required?

Does the facility require an anteroom or airlock? (The certification guidelines relevant for the facility will indicate whether an anteroom or airlock is required.)

Yes ☐	→ Go to **Question 9**
No ☐	→ Go to **Question 10**

Question 9

Anteroom / Airlock present?

If the answer to Question 8 is YES, does the facility have an anteroom / airlock?

Yes	☐	No	☐

If YES, what is/are the room number(s) for the anteroom(s)/airlock(s)?

Room number(s):	

If NO, please explain what alternative arrangements are proposed to manage any risks associated with not having an anteroom / airlock:

Question 10

Facility floor plan

Please attach a formal floor plan of the facility that shows sufficient detail to enable the OGTR to evaluate whether the facility has the required specifications.

At a minimum, ensure the following is shown:

- *allocated room numbers (if applicable);*
- *all doorways and doors;*
- *emergency exits;*
- *any lifts, stairs or ramps between levels inside the building;*
- *if certification is sought for one or more rooms within a larger area, the boundary of the facility (doors and walls) as well as any adjoining areas and their doors; if certification of a whole building, or the majority of a building, the entire floor plan.*

When applying for certification of facilities that require anterooms or airlocks the anteroom(s)/airlocks(s) must be clearly indicated. If an adjoining corridor or another certified or non-certified room is proposed to perform the function of an anteroom, the floor plan must show all doors, lifts, stairs or ramps, and any other relevant details that may compromise the functioning of the corridor or room as an anteroom.

Floor plan attached?	Yes		No	

Section 3
Facility Inspection

If applying for certification of a:

- PC1 Facility
- PC2 Animal Facility
- PC2 Aquatic Facility
- PC2 Constant Temperature Room
- PC2 Invertebrate Facility
- PC2 Laboratory
- PC2 Large Grazing Facility
- PC2 Plant Facility

→ **Complete Section 3 Part A**

If applying for certification of a:

- PC2 Large Scale Facility
- PC3 Facility
- PC4 Facility

→ **Complete Section 3 Part B**

Part A:

Complete this Part in applications for:

- PC1 Facility
- PC2 Animal Facility
- PC2 Aquatic Facility
- PC2 Constant Temperature Room
- PC2 Invertebrate Facility
- PC2 Laboratory
- PC2 Large Grazing Facility
- PC2 Plant Facility

The facility must be inspected by a person who has acquired, through training, qualifications or experience, or a combination of these, the knowledge and skill enabling that person to assess compliance with the requirements for certification of a physical containment facility. The applicant is responsible for choosing an appropriate person to do the inspection. The inspection could be conducted by, for example, an IBC member, a contractor, an independent expert, an employee, or anyone else considered by the organisation to be appropriate. The OGTR does not provide any endorsement of any individuals or organisations to conduct inspections and keeps no details of appropriate persons or organisations.

Question 11

Has the facility been inspected by an appropriate person as outlined above?

Yes ☐ No ☐

Question 12

Does the facility meet all requirements contained in the relevant certification guidelines?

Yes ☐ No ☐

If NO, please provide details of:

- which requirements in the relevant guidelines are not met; and
- what strategies you suggest implementing to manage any risks that may arise or reasons why it is considered that the requirement or condition is not necessary to achieve containment of the GMOs.

Part B:

Complete this Part in applications for:

- PC2 Large Scale Facility
- PC3 Facility
- PC4 Facility

A report of the inspection must be provided to support the application for these facility types. The report must address the extent of compliance with the requirements for certification for the specific facility type/PC level being applied for. The inspection could be conducted by, for example, an IBC member, a contractor, an independent expert, an employee, a third-party assessor, or anyone else considered by the organisation to be appropriate. The OGTR will arrange an independent inspection of the facility in addition to the applicant organisation's inspection.

Inspection checklists are available on the OGTR website.

Only a single checklist should be submitted even if the facility is inspected by more than one person.

Inspection Report/Checklist attached?	Yes		No	

Please list here any other attachments to the application. (Please refer to the relevant guidelines for the required information/attachments).

Please provide any other information that may assist the OGTR in making a decision about this application.

Section 4
Declarations

Declaration of the organisation submitting this application

This declaration must be completed and signed by the CEO (or equivalent), or a person with the authority to sign on behalf of the organisation.

I DECLARE THAT:

- I am a person authorised to submit this form;
- to the best of my knowledge, the information supplied on this form and any other attachment(s) is not false or misleading;
- I am aware that the making of a false or misleading statement may be punishable by imprisonment or a fine under the *Gene Technology Act 2000* and corresponding state law;

Printed name:		Signature:	
Job title:		Date:	