Australian Government
Department of Health and Ageing
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

Paragraph 14(1)(a) of the *Gene Technology Regulations 2001* (the Regulations) and equivalent provisions in corresponding State law specifies the timeframe within which the Regulator must consider and decide on an application for certification. This timeframe is 90 working days after the day the application is received by the Regulator.

Applicants should note that days on which the Regulator is awaiting additional information from the applicant do not count as part of the timeframe given above.

Confidentiality

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

Ethics

The National Framework of Ethical Principles in Gene Technology 2012 (Ethics Framework) has been developed by the Gene Technology Ethics and Community Consultative Committee (GTECCC) to provide a national reference point for promoting ethical conduct in gene technology, consistent with the national regulatory system administered by the Gene Technology Regulator. It replaces the 2006 National Framework for the Development of Ethical Principles in Gene Technology.

The Ethics Framework provides guidance for organisations and individuals and sets out key principles and values to inform and support the consideration of ethical issues relevant to all aspects of gene technology. The Ethics Framework is also intended to provide assurance to the Australian community that not only are any risks involved in gene technology properly managed but that ethical issues are also properly considered.

The OGTR encourages organisations and individuals to refer to the Ethics Framework and to make it available to those involved in the conduct or oversight of gene technology work. The Ethics Framework is available from the OGTR website.

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

- On the OGTR website, starting from 'Forms and Guidelines', you can find explanatory documents about the certification process and the OGTR's physical containment (PC) levels and facility types, as well as individual guidelines for each facility type; or
- Contact the Office of The Gene Technology Regulator 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:

- 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 Level 1, Pharmacy Guild House, 15 National Circuit, BARTON ACT 2600.

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

Acknowledgement of receipt

If you have not received any communication acknowledging the receipt of your application within two weeks, 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 with any 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)		Surname:			
First name:		Preferred first name:			
Phone number:		Mobile:		Fax:	
E-mail address:					
Position title:					
Organisation: (for postal delivery)					
Postal address:					
Postal locality: (City/Suburb/Location)		State:			
Postcode					

Question 2

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

Personal title: (eg Ms/Mr/Dr)		Surname:			
First name:		Preferred first name:			
Phone number:		Mobile:		Fax:	
E-mail address:					
Position title:					
Organisation: (for postal delivery)					
Postal address:					
Postal locality: (City/Suburb/Location)		State:			
Postcode					

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 (Animal/Laboratory/Plant)
- ☐ PC1 Large Grazing Animal Facility
- ☐ PC1 Large Scale Facility

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

- ☐ PC3 Animal Facility
- ☐ PC3 Invertebrate Facility
- ☐ PC3 Laboratory
- ☐ PC3 Plant Facility

- ☐ PC4 Facility

Question 4

OGTR certification

Is this facility currently certified by the Regulator under another certification number (*e.g.* is the certification held by another organisation; is it certified as both PC3 and PC2; 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	

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 usually follow the following format, which generally starts from the smallest identifiable component and ends with the largest:

> Room number(s); Facility title; 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, Bacterial Culture Laboratory, Level 1, George Hamblin Building (#25), University of Manangatang.

Room number(s):			
Facility title: (if applicable)			
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

Number of entrance doors

Doors that are used to enter and leave the facility will require an adhesive OGTR door sign and, where relevant, a biohazard sticker on the non certified side of the door, to alert people that they are entering an area certified by the Gene Technology Regulator. The OGTR generally does not require labels on doors of rooms that can only be accessed from within the certified facility. For example, if there is a non certified room located inside a certified facility, e.g. an office, storeroom or equipment room, the OGTR does not require a label on the door of the non-certified room. Emergency exits and doors that are not in use do not require a door sign.

Number of entrance doors to the facility:	

Question 11

Facility floor plan

Please attach a floor plan or sketch of the facility. A formal floor plan is preferred but a sketch map will suffice if it shows sufficient details to enable the OGTR to evaluate whether the facility has the required physical barriers. At the minimum, the floor plan should show allocated room numbers (if room numbers exist) and all doorways and doors in the facility.

If certification of a whole building, or the majority of the building, is being sought, the entire floor plan will be required. If certification is sought for one or more rooms within a larger area, the plan or sketch must show the boundary of the facility (doors and walls) as well as any adjoining corridors and their doors.

If there are any lifts, stairs or ramps between levels (inside the building), or openings into the facility or adjoining areas/corridors, they must be indicated as they may have a significant bearing on the approval of the application.

When applying for certification of facilities that require anterooms or airlocks the anteroom(s)/airlocks(s) must be clearly indicated.

In relevant PC2 facilities, 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. Supporting information must also be supplied to indicate any risks that might arise from using the adjoining corridor or other room as the anteroom. If there is any doubt about this, it is recommended you contact the OGTR to discuss your proposal prior to submitting the application.

Floor plan attached?	Yes		No	

Section 3
Facility Inspection

If applying for certification of a:

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

→ **Complete Section 3 Part A**

If applying for certification of a:

- PC1 Large Scale Facility
- PC2 Large Scale Facility
- PC3 Animal Facility
- PC3 Invertebrate Facility
- PC3 Laboratory
- PC3 Plant Facility
- PC4 Facility

→ **Complete Section 3 Part B**

Part A:

Complete this Part in applications for:

- PC1 Facility (Animal/Laboratory/Plant)
- PC1 Large Grazing Facility
- PC2 Animal Facility
- PC2 Aquatic Facility
- PC2 Constant Temperature Room
- PC2 Invertebrate Facility
- PC2 Laboratory
- 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 12

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

Yes ☐ No ☐

Question 13

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 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:

- PC1 Large Scale Facility
- PC2 Large Scale Facility
- PC3 Animal Facility
- PC3 Invertebrate Facility
- PC3 Laboratory
- PC3 Plant 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.

The OGTR is willing to undertake joint inspections with the applicant organisation's inspectors and/or third party inspectors for DAFF Biosecurity. Please contact the OGTR well in advance of anticipated/proposed inspection dates to make arrangements for this to occur.

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 duly authorised to sign this declaration;
- the information supplied on this form and any other attachment is true and correct; and
- 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* or corresponding state law.

Printed name:		Signature:	
Job title:		Date:	