



Australian Government

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

# Application for the Suspension of a 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

***Note:** If your application contains Confidential Commercial Information, please contact the OGTR on 1800 181 030 (ask for the Application Entry Point section) or email [ogtr.applications@health.gov.au](mailto:ogtr.applications@health.gov.au)*

Time taken to complete this form:

| Hours                | Minutes              |
|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> |

# General Instructions

---

## ***Application for suspension of a certification***

This application is for the suspension of a low- or high-level containment facility currently certified under the Guidelines for the Certification of Physical Containment Facilities issued under the *Gene Technology Act 2000* (Commonwealth) (the Act) and, as applicable, corresponding state legislation. A low-level facility consists of a physical containment level 1 or 2 facility (PC1 or PC2), while high-level containment facility consists of a physical containment level 3 or 4 or a PC2 large scale (PC3, or PC4 or PC2 large scale facility).

The Gene Technology Regulator (the Regulator) needs the information you provide in this form to assist in determining whether to suspend the facility.

An application for the suspension of certification must be made prior to any structural changes that will affect the containment of GMOs in the facility. The OGTR will make an assessment of the requested suspension and then issue an email confirming the approval/refusal of the suspension application. Please be aware that the conditions of certification continue to apply until you have received written approval of the suspension application from the Regulator.

## ***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***

There are no statutory timeframes applicable to applications to suspend certifications. However, the OGTR has an administrative timeframe of 3 working days for the completion of suspension applications. Suspension of high-level certifications may exceed the administrative timeframe. However, they are typically completed within 10 working days.

If the suspension application is associated with a variation application, then an administrative timeframe of **90 working days** applies.

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 suspension of the certification. The Regulator may require you to provide additional information. If this is necessary, you will be notified of the additional information required.

The option to request a suspension **within** 3 working days, is reserved for genuinely urgent applications. In cases such as this, please call the OGTR on 1800 181 030 (free call within Australia) to confirm your requirements. For all other circumstances, the administrative processing time applies. While we will do our best to accommodate any requests for expedited applications, we cannot guarantee a reduced processing time.

Please note that working days are Monday to Friday, between the hours of 09:00am and 05:00pm and exclude ACT public holidays.

### **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 the Gene Technology Ethics and Community Consultative Committee (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 OGTR's Privacy and personal information [web page](#). The OGTR's 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 3 ('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 the form with wet signature visible in Section 3; or
- if the person transmitting the e-mail is authorised to sign the application, they can include a statement in their e-mail stating that they are a person duly authorised to sign the application; or
- the form can be attached to the e-mail after being digitally signed.

### **Further information**

- Further information is available on the OGTR [website](#).
- The OGTR can be contacted by telephone on 1800 181 030 or e-mail at [ogtr@health.gov.au](mailto: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](mailto:ogtr.applications@health.gov.au); or

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 five working days of submission, please e-mail [ogtr.applications@health.gov.au](mailto: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. Once a decision is made on the application, this person will be notified of the decision.

|   |                     |
|---|---------------------|
| Personal title, e.g. Ms/Mr/Dr:            | Select a Title      |
| Given or Preferred Name:                  | Enter name          |
| Surname:                                  | Enter surname       |
| Phone number:                             | Enter phone number  |
| Additional contact number (If applicable) | Enter phone number  |
| Email address:                            | Enter email address |
| Additional email address (If applicable)  | Enter email address |

#### Facility contact (for high level certifications)

|   |                          |
|---|--------------------------|
| Tick if same as application contact       | <input type="checkbox"/> |
| Personal title, e.g. Ms/Mr/Dr:            | Select a Title           |
| Given or Preferred Name:                  | Enter name               |
| Surname:                                  | Enter surname            |
| Phone number:                             | Enter phone number       |
| Additional contact number (If applicable) | Enter phone number       |
| Email address:                            | Enter email address      |
| Additional email address: (If applicable) | Enter email address      |

## Section 2

### Facility Details

---

#### Question 2

##### Application details

Please provide the certification number, level and type, and reason for suspending the facility.

| OGTR certification number | PC level & facility type | Reason for suspension |
|---------------------------|--------------------------|-----------------------|
| Cert-XXXX                 | E.g., PC2 Laboratory     | Enter Reason          |

(If applying for multiple certifications please add additional rows)

#### Question 3

##### Facility decontamination

For this to be considered a complete application, the statement below must be declared. Incomplete applications cannot be submitted. If you wish to discuss submission of an incomplete application, you must contact the OGTR by phone 1800 181 030 or email [ogtr.cdes@health.gov.au](mailto:ogtr.cdes@health.gov.au).



I declare that the facility is ready to be suspended immediately. All the GMOs have been removed, destroyed or appropriately stored as per the Regulator's [Guidelines for the Transport, Storage and Disposal of GMOs](#), and the facility has been decontaminated.

Stating that the facility has been decontaminated and the GMOs stored appropriately is taken as a legal declaration, and that providing false or misleading information is an offence under the *Gene Technology Act 2000*.

## **Question 4**

Are any of the following changes required during the period of suspension that might warrant a variation to certification?

- Extend the period of the certification
- Change to the area covered by certification
- Change the details in the facility description or other details
- Change to the version of the Guidelines that applies to the certification
- Other

If so, please lodge a separate variation application following the instructions on our [website](#), prior to lodging a suspension application.

Please provide the OGTR reference number for the variation application if known:

Enter OGTR Reference  
Number

Please list here any other changes to the facility.

## **Question 5 (for high level certifications)**

Please provide documents to support the suspension application such as a decontamination report or method used to decontaminate the facility.

Please attach any other documents you wish to add this application form when submitting.

Files you attach with this form via email must:

- be in \*.xls \*.xlsx \*.pdf \*.doc \*.docx \*.jpg \*.jpeg \*.tif \*.tiff \*.png \*.zip format
- each file must be no larger than 20MB
- in total all files must not exceed 20MB

## **Question 6 (optional)**

### **Additional information**

Please provide any other information you wish to add that may assist the Regulator in making a decision about your application.



Please attach any other documents you wish to add to this application form when submitting.

Files you attach with this form via email must:

- be in \*.xls \*.xlsx \*.pdf \*.doc \*.docx \*.jpg \*.jpeg \*.tif \*.tiff \*.png \*.zip format
- each be no larger than 20MB
- not exceed 20MB in total of all attached files

## Section 3

### Declarations

---

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;
- by including my name on this form it is deemed to be my signature for the purpose of this form.

|               |                               |
|---------------|-------------------------------|
| Printed name: |                               |
| Signature:    |                               |
| Date:         | Click or tap to enter a date. |