Australian Government
Department of Health
Office of the Gene Technology Regulator

Application to vary a DIR licence

(licence for dealings involving intentional release of a GMO into the environment)

Licence number:	DIR Enter number
Licence holder:	Enter name
Licence title:	Enter title

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

☐ Yes ☐ No

If any information provided is covered by a previous CCI application(s) or declaration(s), please provide:

CCI application number(s):	Enter numbers
Organisation name(s):	Enter name

If any information provided is covered by previous CCI declaration(s), and can now be made available to the public, please contact the Office of the Gene Technology Regulator (OGTR) to have the declaration revoked.

Time taken to complete this form:	Enter	hours	Enter	minutes

Information for applicants

This application form is for the variation of a licence for dealings involving intentional release (DIR) of a GMO into the environment under the *Gene Technology Act 2000* (the Act).

Before making a variation application, licence holders should consult the OGTR's *Policy on scope for variation of GMO licences* for guidance on types of changes that are or are not likely to be considered as variations. If you are unsure whether the proposed change to the licence is suitable as a variation request, please contact OGTR (details below).

This form should not be used for requesting a transfer of a licence to a new organisation, or surrender of a licence. OGTR's policy on surrendering or transferring a DIR licence can be found on the OGTR Operational policies webpage.

All parts and questions must be completed unless otherwise directed on the form. If any information is attached rather than entered into the form, the attachments must be clearly referenced in the form.

If you wish to protect any information on this form from public disclosure, you must also fill out an *Application for declaration that specified information is confidential commercial information (CCI)* form. Please submit it together with this *Application to vary a DIR licence form*.

Further explanatory material with respect to the information requirements associated with an *Application for declaration that specified information is CCI* is provided on the form.

What will we use the information provided in this form for?

The Gene Technology Regulator (the Regulator) will apply the risk assessment process used in current Risk Assessment and Risk Management Plans (RARMPs), based on the *Risk Analysis Framework*, to identify any increase in the level of risk or any additional risks to those considered in the RARMP prepared for the original licence application or other relevant RARMPs (ie RARMPs for related organisms and dealings). Please note that requested variations that could give rise to additional risk(s) may require a new licence application.

The Regulator may request further information from a licence holder in regard to a variation application. The Regulator must also consult any appropriate local councils.

Acknowledgement of receipt

Once the variation application is received, you will be notified of the assigned OGTR identifier (Var xxxx). Please use this identifier in any correspondence regarding the variation application. Please contact us if we have not confirmed receipt within two weeks of submission.

Timeframe for a decision on a variation application

Under Regulation 11A of the Gene Technology Regulations 2001, the Regulator must vary or refuse to vary the licence within 90 working days of receipt of a variation application (weekends and ACT public holidays are excluded).

We may ask you for additional information in relation to your application. Any days on which the Regulator cannot proceed with decision making while awaiting information requested from the applicant do not count for purposes of determining the end of the decision-making period.

Please note that the dealings in the licence, as requested to be varied, cannot commence unless and until approval is received from the Regulator. In accordance with licence conditions, once a licence is varied, the licence holder is required to obtain signed and dated statements from persons covered by the licence that they have been informed of any applicable licence conditions as varied and that they understand and agree to be bound by the licence as varied.

Queries

Please contact the OGTR by:

- **telephone** (free call): 1800 181 030
- **email**: ogtr@health.gov.au

Personal information

Personal information is collected by the OGTR to enable the 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 (APP) set out in the *Privacy Act 1988*. More information can be accessed at the OGTRs Privacy and personal information web page. The OGTR 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 APP can be made.

1. Contact details for the application

1.1 Details of the person the OGTR can contact regarding this variation application.

Surname:	
Preferred first name:	
Personal title, eg Ms/Mr/Dr:	
Job title:	
Organisation:	
Phone number:	
Email address:	

2. About the variation

2.1 Describe the variation requested and provide details of all dealings proposed to be varied. If the licence is for a limited and controlled release, specify if any changes to the limits and controls required by the licence are proposed.

Enter details

If any information is submitted as an attachment to this form this must be clearly referenced in the text boxes on the form.

Note: If the original licence application was for a limited and controlled release, the Regulator must not vary the licence unless satisfied that the varied licence would also meet the conditions for a limited and controlled release.

2.2 Provide details of the reason(s) for the variation request

Enter details

3. Risk assessment information

3.1 Would the requested variation give rise to any additional risks to human health and safety or the environment, or to an increase in the level of risk, as compared to that assessed for the original licence application?

☐ Yes ☐ No

3.2 Please provide supporting evidence and references if available:

Enter details

Note: The Regulator must not vary a licence if satisfied that the RARMP prepared for the original licence application or another relevant RARMP did not cover the risks posed by the dealings proposed to be authorised by the varied licence. The Regulator also must be satisfied that any risks posed by the proposed dealings are able to be managed so as to protect the health and safety of people and the environment before varying a licence.

4. Declaration

Note: Variation applications must be made by the licence holder. In the case of corporate entities who are licence holders, the request must be made by someone authorised by that entity to make such requests on its behalf.

I declare that:

- I am duly authorised to submit this application; and
- to the best of my knowledge, the information supplied on this form and any other attachment(s) is not false or misleading.

Print name:	Print name
Signature*:	……
Job title:	Enter job title
Date:	Select date

Note: It is a criminal offence for a person to give information to the Regulator that the person knows to be false or misleading.

**** If this application is submitted by email sent by the authorised person named here, a signature is not required***

5. Lodging the application

Electronic submission is preferred, however applications can be lodged in hard copy.

- **email** to ogtr.applications@health.gov.au
- **mail** to: Office of The Gene Technology Regulator, MDP 54, GPO Box 9848, CANBERRA, ACT 2601

Please keep a copy of the application for your records.

Note: Emails containing sensitive information (such as confidential commercial information (CCI)), will be transmitted via an unclassified internet connection and will not be protected during the process. If you wish to securely transmit sensitive information electronically, please contact this office to arrange for the information to be submitted via the Department of Health's data portal.