Australian Government
Department of Health
Office of the Gene Technology Regulator

Application to vary a DNIR licence

(licence for dealings not involving intentional release of a GMO into the environment)

Licence number:	DNIR 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 variation of a licence for dealings not involving intentional release (DNIR) of a GMO into the environment under the *Gene Technology Act 2000* (the Act). More information on how to fill out this form is available in the document *Guidance on making an application to vary a DNIR licence*.

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 unsure whether a proposed change to the licence is suitable as a variation request, please consult with your IBC in the first instance. IBC members are welcome to contact the OGTR for advice.

In making an application to vary a DNIR licence, licence holders should address all the relevant information requirements detailed in the document *Guidance on making an application to vary a DNIR licence*. If appropriate information is not provided, the Regulator may request further information, and a decision on the variation application may be delayed (see *Timeframe for decision*, 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 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 DNIR 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.

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 decision on 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 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 (APP) 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 APPs can be made.

1. Contact details for the application

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

Surname:	Enter name
Preferred first name:	Enter first name
Personal title, eg Ms/Mr/Dr:	Enter title
Job title:	Enter job title
Organisation:	Enter organisation
Phone number:	Enter phone number
Mobile number:	Enter mobile number
Email address:	Enter email address

2. Category of requested variation

Please mark each applicable category, keeping in mind that changes in one category can impact other categories. Detail about the requested variation must be provided at question 3.

☐ A. Extend the period of the licence
Note: When requesting variation for another purpose, licence holders should consider requesting an extension if the DNIR licence has less than 12 months remaining before expiry.

☐ B. Add one or more GMOs or class of GMOs, genes, classes of genes or vectors to the licence.

☐ C. Add organisms to be used in association with the GMOs (e.g. cells, tissues, animals or plants to be used as hosts for GM microorganisms).

☐ D. Remove one or more GMOs, genes/classes of genes, vectors or organism used in association with the GMOs (host) from the licence.

☐ E. Change the description of dealings listed in the licence.
Note: This relates to the licence condition under the heading Dealings authorised by this licence.

☐ F. Include large scale dealings (if not already authorised by the licence)
Note: Large scale dealings are any dealings involving 25 litres or more of GMO culture in any one vessel.

☐ G. Change facilities listed in the licence.

☐ H. Change the conditions of the licence relating to transport, storage, or disposal/decontamination of the GMOs.

☐ I. Supply of a GMO to another organisation.

☐ J. Change work practices listed in the licence.

☐ K. Other.

3. Details of requested variation and supporting information

Provide details of the requested variation and relevant supporting information, as outlined in the document Guidance on making an application to vary a DNIR licence *for each of the variation categories selected above.*

Enter details and supporting information as outlined in the guidance document

If any information is attached rather than entered into the form, the attachments must be clearly referenced here.

Note that the Regulator's practice is to exclude, where possible, any dealings that may be conducted as notifiable low risk dealings (NLRDs) or exempt dealings from DNIR licences. Therefore, when preparing a variation application, licence holders are encouraged to review both current and proposed dealings to identify and remove any NLRDs and exempt dealings. NLRDs must be conducted in accordance with the requirements of the Gene Technology Regulations 2001 (the Regulations), including prior assessment by an IBC.

4. Risk assessment and risk management information

Please provide a statement about any expected changes to risks to human health and safety or the environment, as compared to risks posed by dealings conducted according to the current licence. If risks may be increased by the proposed variation (i.e. if either the likelihood of exposure may be increased, or the consequences of exposure may be more severe), information on how the risks will be managed should also be provided. Where relevant, please provide supporting

evidence/information to enable the Regulator to assess risks associated with the proposed variation, and any changes to risk management, so as to be satisfied that risks can be managed to protect people and the environment.

Enter statement about risk and risk management, and supporting information where relevant

If any information is attached rather than entered into the form, the attachments must be clearly referenced in the form.

5. References

If you have cited references in your answers to questions 3 or 4, please list the cited references and provide copies (preferably electronic).

List cited references and attach copies

If any information is attached rather than entered into the form, the attachments must be clearly referenced here.

6. 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***

7. Lodging the application

Electronic submission is preferred, however applications can also 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.