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

Guidance on making an application to vary a DNIR licence

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

General information for applications

The Gene Technology Regulator (the Regulator) may vary a GMO licence on application from the licence holder. This document provides guidance on the information required in the *Application to vary a DNIR licence* form for a range of common variation categories. The information provided in the form must 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. A well-prepared application minimises the need for us to contact you to ask for further information, and assists us in formulating appropriate licence conditions.

Information on the OGTR's policy on the variation of GMO licences, including on types of changes that are or are not likely to be considered as variations, can be found in the OGTR's *Policy on scope for variation of GMO licences*. If you are unsure whether the changes you are proposing are able to be authorised by way of a variation, please consult with your IBC in the first instance. IBC members are welcome to contact the OGTR for advice (contact details below).

Note that the Regulator's current practice is to exclude any dealings that may be conducted as notifiable low risk dealings (NLRDs) or exempt dealings from DNIR licences. Therefore, when preparing a variation application, it is suggested that both current and proposed dealings be reviewed 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.

Timeframe for decision on a variation application

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 variation 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.

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.

If you wish to securely transmit sensitive information (such as confidential commercial information, CCI), please contact the OGTR to arrange for the information to be submitted via the Department of Health's data portal. Note that emails are transmitted via an unclassified internet connection and information will not be protected in the process.

Acknowledgment 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. If you have not received an identifier within two weeks, please e-mail ogtr.applications@health.gov.au or telephone 1800 181 030.

Queries

Please contact the OGTR by:

- **telephone** (free call): 1800 181 030
- **email**: Contained Dealings Evaluation Section: ogtr.cdes@health.gov.au

Category and details of requested variation (Questions 2 & 3)

At **Question 2** of the DNIR variation application form, applicants must indicate all relevant variation categories using the check-boxes.

At **Question 3**, details of the variation and relevant supporting information must be provided.

The type of information required is described below for each of the variation categories.

Information does not need to be provided in the same order as listed in this guidance, or separately for each category of variation, although doing so may help you ensure that all relevant information is provided.

Your variation application should provide a clear description of the GMOs and/or activities that would be authorised by the proposed licence variation, along with information to assist the Regulator in assessment of any associated risks to people or the environment and management of those risks.

A. Extension to the period of the licence

Indicate the period of extension that is requested, noting that if the application is approved, the Regulator's current practice is to extend DNIR licences for a maximum of 5 years.

Additional variation categories that may apply:

When extending a licence, it is advisable to review the GMOs and dealings to ensure they match the work that is expected to be conducted over the proposed period of the extension. Please also note that the Regulator's current practice is to exclude from DNIR licences any dealings that may be conducted as NRLDs or exempt dealings, and the OGTR gives particular attention to this when extending a DNIR licence. Therefore, when preparing the variation application, both current and any new proposed dealings should be reviewed to identify and remove any NLRDs and exempt dealings. If GMOs or dealings to be conducted are different to those already listed in the current licence, you should also include variation categories B (add GMOs), D (remove GMOs or host organisms) and/or E (changes to the description of dealings) in your variation application.

Any NLRDs removed from a licence must only be conducted in accordance with the requirements of the Gene Technology Regulations 2001 (the Regulations), including prior assessment by an IBC.

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

The following information should be provided:

(a) How does each new GMO or class of GMO relate to GMOs already authorised by the current licence?

(b) Which paragraphs of Schedule 3 Part 3 of the Regulations apply to the proposed dealings with the new GMOs?

(c) A description of each new GMO or class of GMO, including the following details:

- parent organism
- the donor organism for any introduced nucleic acid
- if the donor nucleic is from a toxin producing organism, does it or may it encode a toxin, and if so what is the LD_{50} (if known)?
- how the modification will be/has been made

- the resultant modified trait(s)
- how the modified trait might effect on the behaviour of the parent organism in a host or in the environment
- whether the modification can impart any oncogenic or immunogenic property to the GMO or increase its capacity to cause harm as compared to the parent organism
- whether practical treatment of any disease or abnormality caused by the organism will be impaired by the genetic modification.

(d) What organisms, tissues or cells are to be used in association with the new GMO(s) (hosts for GM microorganisms)?

Additional variation categories that may apply:

If host organisms to be used in association with new GMOs are different to those used with GMOs already authorised by the current licence, you should also include variation category C (Additional organisms to be used in association with the GMOs) in your variation application.

If dealings to be conducted with the new GMOs are different to those already listed in the current licence (under the heading Dealings authorised by this licence*), you should also include variation category E (changes to the description of dealings) in your variation application.*

If transport, storage and disposal/decontamination methods required by the current licence are not suitable for the new GMO(s), you should also include variation category H (change to the conditions for transport, storage, or disposal/decontamination) in your variation application.

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

The following information should be provided:

(a) Which paragraphs of Schedule 3 Part 3 of the Regulations apply to the proposed dealings with the new host organisms to be used in association with the GMOs?

(b) A description of each new host organism, including the following details:

- the name (common and scientific) of the organism
- how the host organism relates to those already listed in the current licence
- the methods proposed for handling the new host organism(s), including (as applicable):
  - how host organism(s) will be exposed to GMOs
  - housing/containment
  - restraint
  - anaesthetisation
  - decontamination of host organism(s) and waste
  - any other relevant handling methods.

(c) If the new host organisms are to be used only with some of the GMOs, provide details of GMO/host combinations.

Additional variation categories that may apply:

If dealings to be conducted with the new GMO/host combinations are different to those already listed in the current licence (under the heading Dealings authorised by this licence*), you should also include variation category E (changes to the description of dealings) in your variation application.*

If work practices not permitted by the current licence are required for a proposed new host, you should also include variation category J (changes to work practices) in your variation application.

If transport, storage and disposal/destruction methods in the current licence are not suitable for the new host/GMO combinations, you should also include variation category H (change to the conditions of transport, storage, or disposal/decontamination) in your variation application.

D. Remove one or more GMOs, genes/classes of genes, vectors or host organisms from the licence

List each GMO/gene/vector/host to be removed from the licence, with references to the relevant GMO numbers in the current licence, and indicate if these GMOs, or GMOs produced using these genes or vectors, were produced under the licence. If they were produced, have the relevant GMOs been destroyed or are they covered by another authorisation (for example another licence or an NLRD)?

Additional variation categories that may apply:

If some dealings listed in the current licence (under the heading Dealings authorised by this licence*) will no longer be applicable, you should also include variation category E (changes to the description of dealings) in your variation application.*

E. Change to the description of dealings listed in the licence

Provide a description of the proposed new dealings or changes to existing dealings, with reference to the dealings listed in the current licence (under the heading *Dealings authorised by this licence*).

Explain how the proposed changes impact on the work to be conducted under the licence (e.g. allow new experimental protocols to be used, new combinations of modifications, new GMO/host combinations).

Note that the Regulator's current practice is to exclude from DNIR licences, where possible, any dealings that may be conducted as NLRDs or exempt dealings. 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.

Additional variation categories that may apply:

If work practices not permitted by the current licence are required for the proposed new dealings, you should also include variation category J (changes to work practices) in your variation application.

F. Include large-scale dealings (if not already authorised by the licence)

Large-scale dealings are defined as cultures of GMOs with volumes greater than 25 litres in any one vessel.

The following information should be provided:

(a) What GMOs are proposed to be grown in large volumes?

(b) What volumes are proposed to grown?

(c) What is the purpose of the large-scale culture? (e.g. what is the product)

(d) How will the large-scale cultures be inoculated, grown, harvested and disposed of?

(e) Which facility/ies will be used for the proposed large-scale culture?

(f) How do you propose to transport, store and dispose of/destroy the GMO(s)?

Additional variation categories that may apply:

Variation category G (changes to facilities or containment measures) is likely to be required in your variation application.

G. Change to facilities listed in the licence

The following information should be provided (as relevant):

(a) If facilities are to be removed from the licence, provide certification number(s), facility type and level.
Note that the licence holder should ensure that facilities suitable for the authorised dealings remain on the licence.

(b) If certified facilities are to be added to the licence:

- provide facility details (certification number, certification holder, facility type, level and certification status)
Note that for a certification that is not held by the licence holder, standard licence conditions require written consent from the certification holder to conduct dealings authorised by the licence in the facility.
- indicate whether or not the facility is a multi-user facility (i.e. the facility is used by personnel other than those conducting the dealings authorised by the licence)
Note: For multi-user facilities, consideration should be given to the need for segregation of the licensed dealings conducted from other work within the facility &/or informing other users about the licensed dealings and their risks.

Additional variation categories that may apply:

If different work practices are appropriate for a proposed new facility, for example because of particular equipment in a new facility or in relation to segregation of activities in a multi-user facility, you should also include variation category J (changes to work practices) in your variation application.

If transport, storage and disposal/destruction methods in the current licence are not suitable for a proposed new facility, you should also include variation category H (change to the conditions of transport, storage, or disposal/decontamination) in your variation application.

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

Please provide the following details, as applicable:

(a) If use of a courier/ transport contractor is proposed to be added, details of the proposed transport, such as the purpose (e.g. import, export, transfer between facilities, supply or disposal), packaging, labelling and how contractors will be informed of relevant licence conditions.

(b) If transport not involving couriers/contractors is proposed, details of packaging and transport arrangements.
Note: Indicating that this would be in accordance with the Regulator's Guidelines for Transport, Storage and Disposal of GMOs would be sufficient.

(c) If use of a waste disposal contractor is proposed, arrangements for collection and transport, method of disposal and how contractors will be informed of relevant licence conditions.

(d) If storage outside the facilities where dealings are being conducted is proposed, details of packaging and storage arrangements.
Note: Indicating that this would be in accordance with the Regulator's Guidelines for Transport, Storage and Disposal of GMOs would be sufficient.

I. Supply a GMO to another organisation

If a GMO is to be supplied to an organisation not covered by the current licence, please provide the following details:

(a) What GMOs are proposed to be supplied?

(b) What is the name of the receiving organisation?

(c) Does the receiving organisation have a DNIR licence or an NLRD to authorise dealings with the GMO(s)?

Additional variation categories that may apply:

If transport methods in the current licence are not suitable for the proposed supply e.g. a courier will be used but is not provided for in the current licence, you should also include variation category H (change to the conditions of transport, storage, or disposal/decontamination) in your variation application.

J. Change to work practices listed in the licence

Describe the proposed work practices to be included in the licence and how the changes will impact the conduct of dealings authorised by the licence.

Note: Information on how these changes impact likelihood of exposure of people or the environment to the GMOs, and how any associated increased risk will be managed, should be provided at question 4 in the variation application form.

K. Other changes to the licence not covered in the previous sections

Describe the proposed variation and how the changes will impact the conduct of dealings authorised by the licence.

Risk assessment and risk management information (Question 4)

The Regulator must not vary a licence unless the risks posed by the varied licence are covered by the RARMP prepared for the original licence application or by another relevant RARMP. 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.

Question 4 of the DNIR variation application form asks for a statement about changes to risks to human health and safety or the environment that may be associated with the proposed variation. For simple changes this may be something like:

> *No change to risk is expected as the new GMOs will have similar properties to those already authorised by the current licence / the new facilities are of the same type and level as those already listed in the current licence / the new work practices provide equivalent risk management.*

However other types of proposed changes may be associated with new or increased risks. For example, if a current licence authorises using GM pathogens in tissue culture, and the proposed variation involves putting the GM pathogens into animals, there will be a change to potential exposure pathways. Information about associated risks and risk management (e.g. work practices) should be provided.

Another example in which risks may be changed is inclusion of dealings by waste disposal contractors, which necessitate transport outside of buildings and disposal by people not familiar with the GMOs. Risks with these activities should be acknowledged, and any relevant risk management measures described.

If risks may be increased by the proposed variation (i.e. if either the likelihood of exposure may be increased or the consequence of exposure may be more severe), information on how the risks will be managed should also be provided. It may be that existing risk management remains appropriate, or that new work practices proposed to be included will manage a risk that would be increased by another proposed change.