

GMO dealing assessment and approval process

Applicant contacts the Institutional Biosafety Committee (IBC) to ask if proposed work is a GMO dealing

If the IBC advises the dealing is NOT a GMO dealing, confirmation is provided to the applicant

If the IBC considers the proposed work to be a GMO dealing, a GMO dealing application is required. Click [here](#) to download the application form

Applicant submits a GMO dealing application form to the IBC

- The IBC secretary can assist with selecting the dealing type(s)
- All personnel involved with the proposed GMO dealings must complete the required training, as indicated in the application form
- For first time applicants, you must provide a brief one-page resume outlining relevant experience and qualifications in relation to GMO work

IBC assessment

- Assessments generally take 2-4 weeks
 - Longer if application revisions are required, or if Office of the Gene Technology Regulator (OGTR) advice is sought

IBC issues the applicant with a **record of assessment (RoA)** which confirms the dealing type and, for exempt and NLRD dealings, authorises the work to commence

Exempt GMO dealing

Exempt dealings are dealings with GMOs that pose a very low risk. They cannot involve any release of a GMO into the environment, such as field trials or commercial releases.

- This dealing is approved for a period of 5 years from the date the RoA is issued
- Amendments can be made by emailing the IBC
- A new GMO dealing application form must be submitted to extend the work before the 5-year expiry

Notifiable Low Risk GMO Dealing (NLRD)

A notifiable low risk dealing (NLRD) is an activity with GMOs that is:

- undertaken in containment, in a facility certified by the Regulator or approved in writing by the Regulator
- assessed as posing low risk to the health and safety of people and the environment provided certain risk management conditions are met.

- The dealing is approved for a period of 5 years from the date the RoA is issued
- Amendments are permitted only if they fall within the scope of the RoA
- A new GMO dealing application form must be submitted to extend the work before the 5-year expiry date

Licensed GMO Dealings

Dealings involving intentional release (DIR)

A DIR is a dealing involving the intentional release of GMOs outside of containment facilities.

Dealings not involving intentional release (DNIR)

A DNIR is a medium-high risk GMO dealing not involving the intentional release of a GMO into the environment.

- These dealings require an OGTR licence application, plus approx. 3 months of internal pre-review. A timeline for licence applications is available on request.
- The IBC secretary will help you to prepare an application form
- OGTR timeframes are as follows:
 - DIR: 150-255 working days
 - DNIR: 90 working days