Australian Government
Department of Health
Office of the Gene Technology Regulator

January 2014
Fact sheet

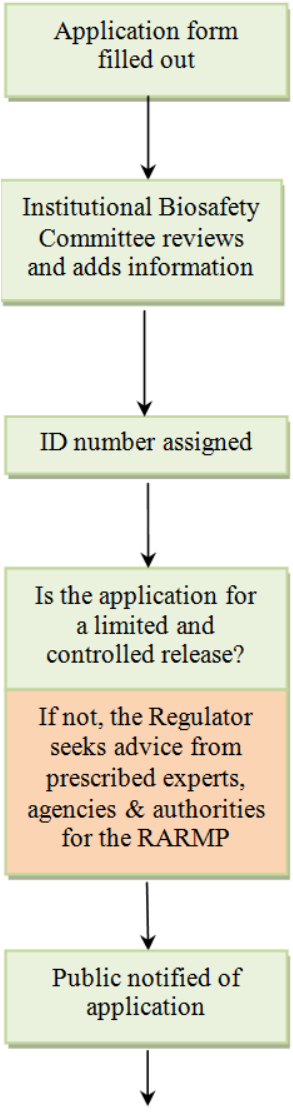
How are licence applications for environmental release of GMOs evaluated?

Dealings involving an intentional release (DIRs) of genetically modified organisms (GMOs) into the Australian environment involve dealings with GMOs **outside** contained facilities. They can range from small-scale field trials ('limited and controlled releases') of GMOs to general/commercial release of GMOs.

DIRs require authorisation, usually a licence, from the Gene Technology Regulator (the Regulator). This is specified in the *Gene Technology Act 2000* (the Act). The Act (Sections 40–67) also sets out a clear process that the Regulator must follow to:

- prepare a risk assessment and risk management plan (RARMP)
- make a decision about whether or not to issue a licence.

General steps of DIR licensing



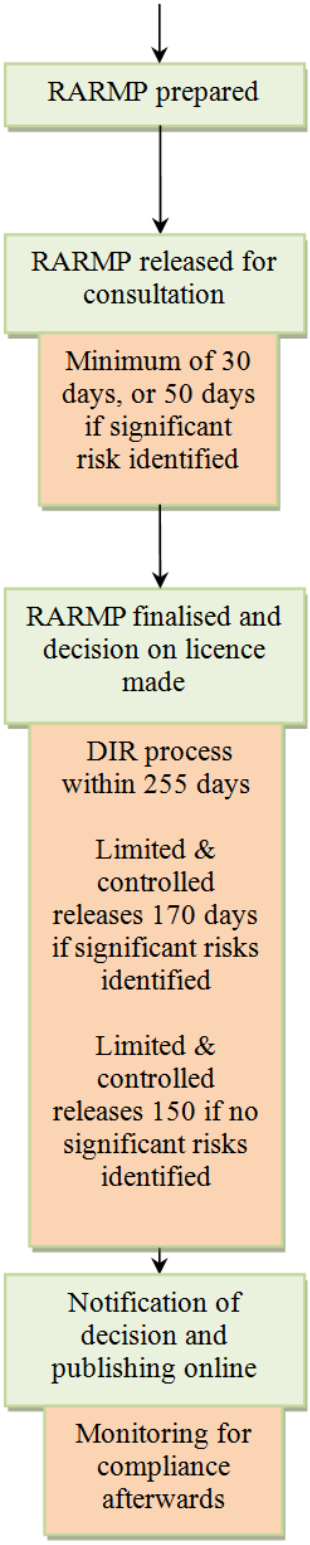
1. Application form filled out
The DIR application forms are available online (www.ogtr.gov.au).

2. Application reviewed/supported by an Institutional Biosafety Committee
In addition to reviewing the application, the Institutional Biosafety Committee adds supporting information before the application is forwarded to the Regulator. Institutional Biosafety Committees are established by an accredited organisation—usually the organisation applying for the licence.

3. Application identification number assigned
Once the application is received by the Regulator it is screened for completeness, acknowledged and a DIR identification number assigned.

4. Limited and controlled release qualification determined
Some DIR applications which are principally for research and meet other criteria for a limited and controlled release application (Section 50A) qualify for a streamlined process. Criteria include limits on the size, location and duration of the release, and controls to restrict the spread and persistence of the GMOs are proposed (i.e. most field trials). The Regulator decides which applications qualify for that process on a case-by-case basis, based on the information in the application. Unless the application qualifies as limited and controlled, the Regulator consults experts, agencies and authorities about matters to consider in the RARMP (Section 50(3)).

5. Public notification given
A summary of the application is prepared by the OGTR. The summary and a notification of receipt of the application is posted on the OGTR website and sent to individuals and organisations who have registered to receive information from the OGTR.



6. Preparation of a RARMP

A risk assessment and risk management plan (RARMP) is prepared for the application, taking into account matters prescribed in the Act and the *Gene Technology Regulations 2001* (Sections 50(1), 51; regulations 9A, 10).

7. Consultation about RARMP

The Regulator must consult the Gene Technology Technical Advisory Committee, prescribed agencies and authorities (Section 52(3)), and the public (Section 52(1)) on all RARMPs prepared for DIR applications. Submissions are directly and indirectly invited through national and regional newspapers, the Australian Government Gazette, the OGTR website and direct mail/email. A minimum of 30 days (50 days, if significant risk is identified) is allowed for submissions.

8. Finalisation of RARMP and decision on licence

The RARMP is finalised, taking into account the advice received about risks to human health and safety and the environment (Section 56). The Regulator also considers the applicant's suitability to hold a licence (Section 57), and licence conditions that may be imposed if licence is issued (Sections 55, 61 – 62). This process informs the Regulator's decision to issue or refuse to issue a licence (Section 56). The Regulator must decide to issue or refuse to issue a DIR licence within:

- 255 working days, or
- 150 days, for applications for a limited and controlled release for which the Regulator has not identified significant risk, or
- 170 days, for applications for a limited and controlled release for which the Regulator has identified significant risk (regulation 8).

The Regulator must not issue a licence unless satisfied that any risks posed by the dealings proposed to be authorised by the licence are able to be managed in a way that protects the health and safety of people and the environment (Section 56).

9. Notification of decision

The applicant; experts, agencies and authorities; and the public are notified of the decision, as well as the decision being recorded in the GMO Record on the OGTR website. For all DIR licences, you can download the RARMP, the licence conditions and other supporting information. If a licence is issued, monitoring to ensure compliance with licence conditions occurs afterwards.

Up to date lists of issued DIR licences and DIR applications currently under consideration are available online, with links to detailed information for each DIR. For further information see Appendix 2 of the OGTR's annual report or our Licence Application & Assessment Process webpage.

If you would like more information about applications to deal with GMOs, please contact the OGTR by:

- email: ogtr@health.gov.au
- free-call: 1800 181 030
- fax: 02 6271 4202
- mail: MDP 54, GPO Box 9848, Canberra ACT 2601.