



December 2010

FACT SHEET

Application assessment process for dealings involving intentional release (DIR) of a GMO into the environment

Under the *Gene Technology Act 2000* (the Act) dealings involving the intentional release of a GMO into the environment require authorisation, usually a licence, from the Gene Technology Regulator (the Regulator). Sections 40 – 67 of the Act establish the process the Regulator must follow in making a decision about whether or not to issue a licence. The generalised steps involved in the DIR licensing process are outlined below.

Application forms for a DIR licence are available on the OGTR website (www.ogtr.gov.au). The completed application must include supporting information provided by an Institutional Biosafety Committee (IBC) established by an accredited organisation, usually the organisation applying for the licence.

Upon receipt, the application is screened for completeness by the OGTR, a DIR identification number is assigned and its receipt is acknowledged. The Regulator then determines if the application qualifies as a limited and controlled release (requiring that its principal purpose is to conduct experiments, and that limits on the size, location and duration of the release and controls to restrict the spread and persistence of the GMOs are proposed; eg most field trials). For all DIR applications a summary of the application is then prepared by the OGTR and public notification of receipt of the application is issued via the OGTR's website and sent to individuals and organisations that have registered to receive information from the OGTR.

Unless the application qualifies as limited and controlled, the Regulator seeks advice from prescribed experts, agencies and authorities on matters relevant to the assessment. A risk assessment and risk management plan (RARMP) is then prepared for the application, taking into account matters prescribed in the Act and the Gene Technology Regulations 2001.

Submissions are sought on the RARMP from prescribed experts, agencies and authorities. Submissions are also invited from the public through notices in national and regional newspapers, the Australian Government Gazette, OGTR website and direct mail to those registered with the OGTR. A minimum of 30 days (50 days if significant risk is identified) is allowed for submissions.

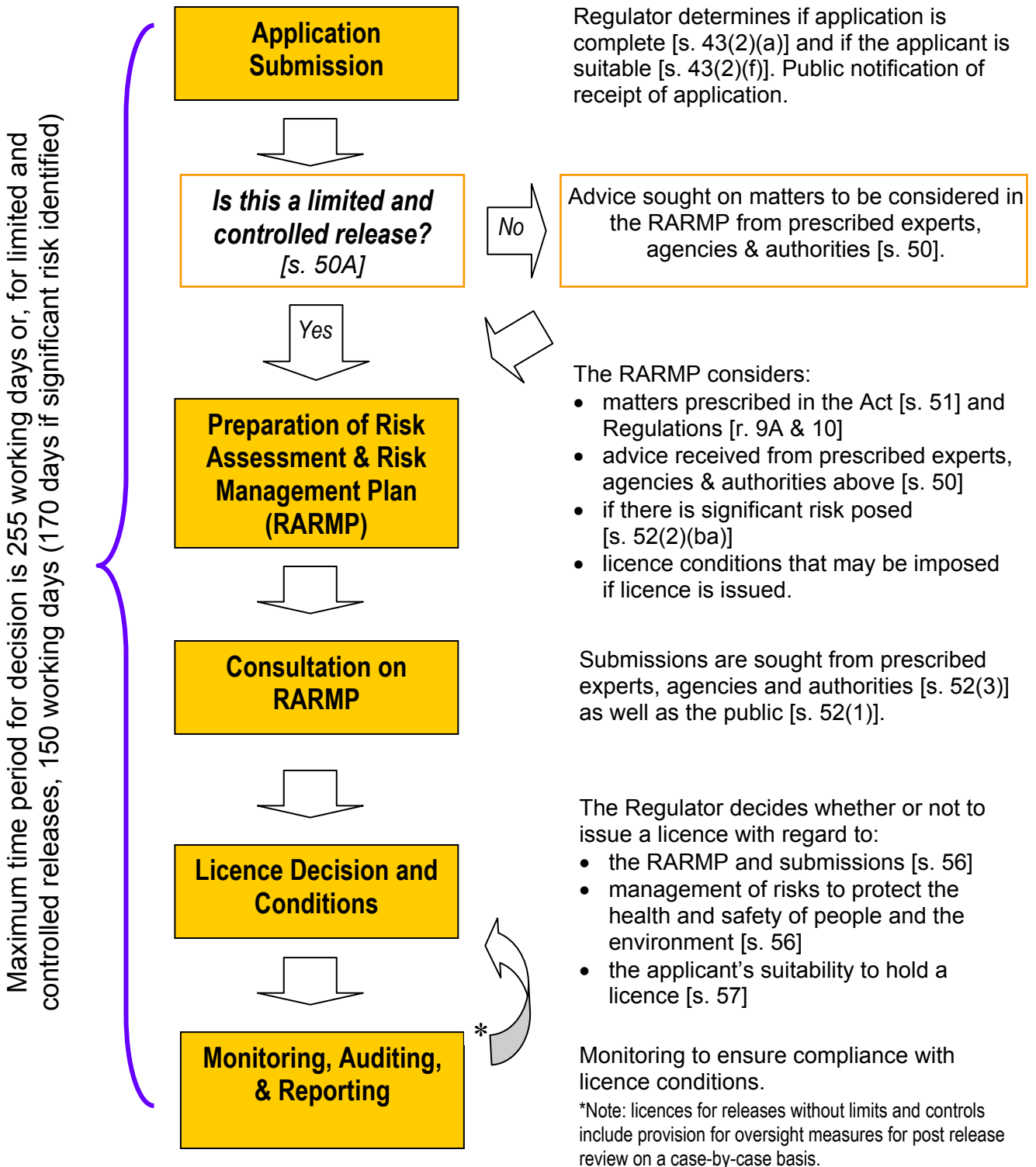
The RARMP is finalised taking into account advice received on risks to human health and safety and the environment, and informs the Regulator's decision to issue or refuse to issue a licence. The Regulator must make this decision within:

- 255 working days (except for limited and controlled release applications), or
- 150 working days (170 working days if significant risk identified) for limited and controlled release applications.

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.

The applicant, prescribed experts, agencies and authorities and the public are notified of the decision. For all DIR licences, the RARMP, licence conditions and other supporting information can be downloaded from the GMO Record on the OGTR website.

Schematic of application assessment process for DIR licence



For further information see Appendix 2 of the OGTR's annual report or the *Licence Application & Assessment Process* page, both found on the OGTR website.