Australian Government
Department of Health
Office of the Gene Technology Regulator

# How we regulate the intentional releases of GM crops and other GMOs into the environment

Gene technology is widely used in Australia: in agriculture, in research, in health and medicine, in education, and in industry.

When gene technology is used to create a genetically modified (GM) plant, animal or other living thing (organism), the genetically modified organism (GMO), for example GM canola, is regulated by the Gene Technology Regulator to protect people and the environment.

The most contentious uses of GMOs in Australia are the use of GM crops and similar releases of GMOs into the environment. Australian gene technology legislation uses the term 'environmental release' to describe applications where the GMO will not be confined to a laboratory, plant house or similar containment facility.

Any proposal to release a GMO into the environment receives intense scrutiny by the Regulator and by the wider community.

This factsheet provides details on how these proposals are assessed. For an overview of other uses of GMOs, for example in schools and research in Australia, visit Genetically modified organisms in Australia.

Release into the environment can include:

- controlled field trials of GM crops
- clinical trials or commercial release of GM medicines
- commercial farming of GM plants (currently only canola, carnations cotton, and safflower have been authorised in Australia).

The Regulator must not issue a licence unless satisfied that any risks are able to be managed in a way that protects the health and safety of people and the environment.

The list of current licences for environmental release can be viewed online at the GMO Record.

## Applying for an intentional release licence

A licence for intentional release of any type is known as a 'Dealings involving Intentional Release' (DIR) licence.

Application forms for a DIR licence are available on the OGTR website.

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 Office of the Gene Technology Regulator (OGTR), a DIR identification number is assigned and receipt is acknowledged.

The Regulator then determines if the application qualifies as a limited and controlled release (primarily experimental with proposed limits on the size, location and duration of the release and controls to restrict the spread and persistence of the GMOs). This is the case for most field trials and clinical trials.

For all DIR applications, a summary of the application is then prepared by the OGTR and the public is notified via the OGTR website. For commercial release applications, the Regulator seeks advice from prescribed experts, agencies and authorities. Public comment is not normally sought at this stage.

A draft risk assessment and risk management plan (RARMP) is prepared by the OGTR for the application.

For all DIR applications, once the draft RARMP has been prepared submissions are sought on the RARMP from prescribed experts, agencies and authorities. Submissions are also invited from the public for a minimum of 30 days (50 days if significant risk is identified). See our factsheet on public participation in assessing gene technology.

The RARMP is then finalised taking into account advice received on risks to human health and safety and the environment. The final RARMP 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, which are 150 working days – or 170 working days if significant risk is identified).

Further reading

Genetically modified organisms in Australia

Genetically modified (GM) crops in Australia

How are genetically modified organisms (GMOs) regulated in Australia?

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Contact us: ogtr@health.gov.au, www.ogtr.gov.au, phone 1800 181 030,
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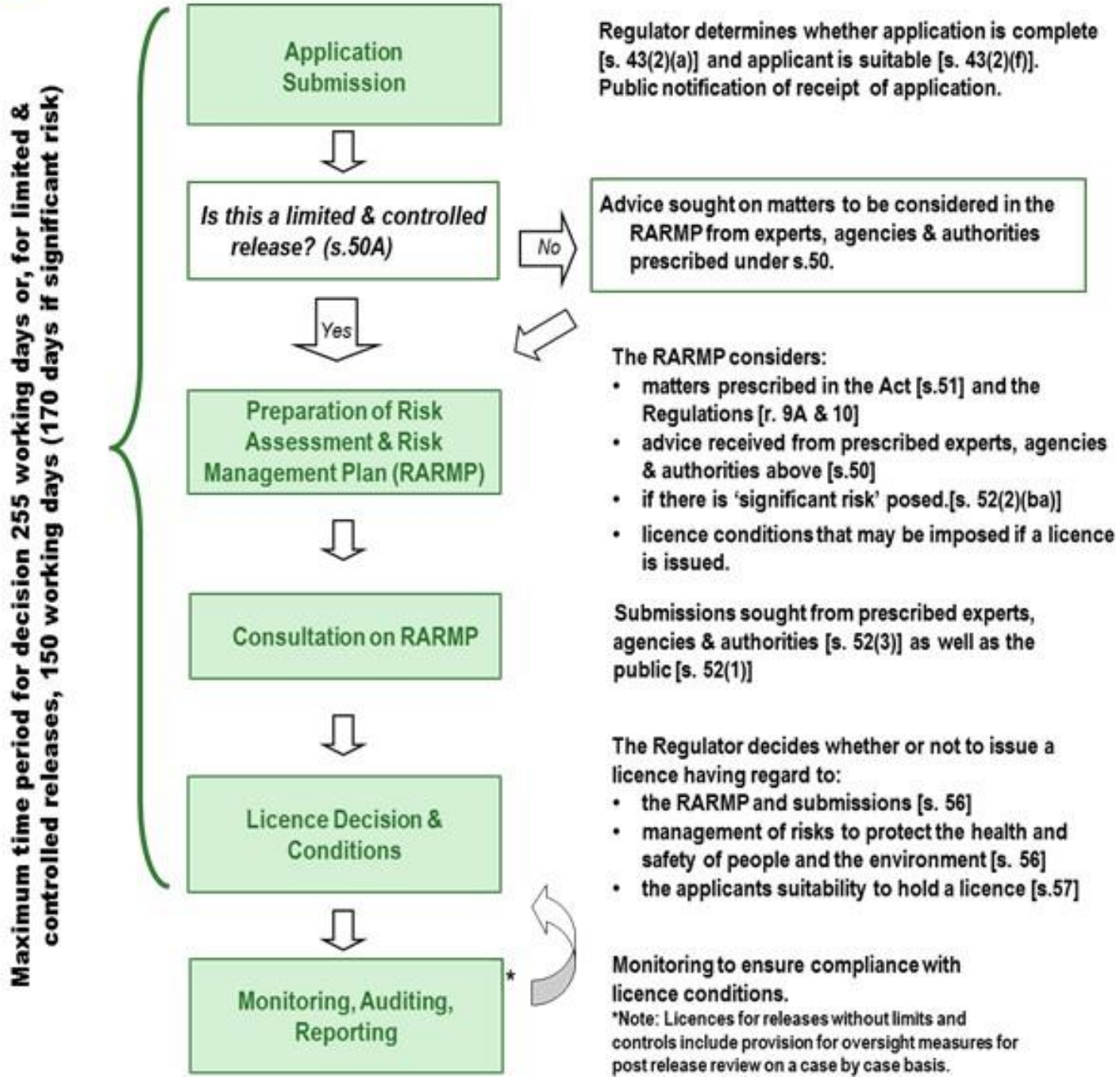


The Regulator will not issue a licence unless satisfied that any risks posed by the dealings proposed to be authorised by the licence are able to be managed in a way that protects the health and safety of people and the environment.

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. The RARMP includes appendices summarising all submissions received and how they were taken into account while finalising the RARMP.

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 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 as summarised in the figure above.