Australian Government
Department of Health
Office of the Gene Technology Regulator

Celebrating 20 Years of OGTR 2001 - 2021

Retrospective report 1

Overview of the scheme

21 June 2021

Contents

Overview of the Scheme

Australia celebrates the 20th anniversary of the *Gene Technology Act 2000* (the Act) on 21 June 2021. On that day, two decades earlier, the legislation to regulate activities involving gene technology came into effect. The Gene Technology Bill 2000 (the Bill) was read in the House of Representatives on 22 June 2000. The Act replaced an administrative system of voluntary controls over dealings with genetically modified organisms (GMOs).

Transition from a Voluntary Scheme to a Legislated Scheme

The oversight of gene technology in Australia began on a voluntary basis with the formation of the Committee on Recombinant DNA that was established by the Australian Academy of Science in 1975. This was followed by the establishment of the Recombinant DNA Monitoring Committee in 1981 within the then Commonwealth Department of Science. Both committees comprised scientific experts with a diverse range of expertise that effectively provided peer review assessment of proposals to conduct experiments with GMOs between 1975 and 1987.

From 1987 through to 21 June 2001, the Genetic Manipulation Advisory Committee (GMAC) oversaw the development and use of gene technology in Australia. GMAC was an independent committee of scientific experts tasked with assessing risks to human health and the environment that may arise from an application of the technology and provided advice on how the risks could be managed. GMAC's predecessors (the Recombinant DNA Monitoring Committee and the Academy of Science on Recombinant DNA) held these responsibilities from 1975 - 1987.

GMAC operated within an administrative system. The Committee's recommendations were sought, and complied with, voluntarily. The compliance with GMAC recommendations was considered to be high. GMAC also provided expert advice on biosafety to statutory authorities that were responsible for product approvals which may have included GMOs and products of GMOs.

In the absence of regulatory powers, GMAC had limited capacity for independent, legally enforceable auditing and monitoring of compliance. There was no legal basis for the imposition of penalties or other action in the event of non-compliance. From an industry perspective, there was no clear path to market for products of gene technology which fell outside the mandate of existing regulators, and there was no certainty about the rules or standards that may have applied to identify or manage risks. From a community perspective, there was inadequate consultation and transparency in relation to decision making and a lack of confidence in the effectiveness of the control system. Recognising those deficiencies, all States, Territories and the Commonwealth collaborated to develop a nationally consistent regulatory system for GMOs. The national regulatory system was developed and informed by extensive consultations with relevant government agencies, as well as with individuals and organisations outside government, including the research and development sector, consumer and environmental groups, primary producers and industry.

In establishing the regulatory scheme, governments sought to recognise and balance the potential of gene technology to contribute to society with community concerns over its development and deployment. The extensive consultation conducted during the development of the regulatory scheme reflects the emphasis placed on community input and participation in the decision making process, and generated strong agreement about what should be included and excluded from the scope of the legislation. There was a broad consensus that the Gene Technology Regulator (the Regulator) should consider only gene technology, and other forms of genetic manipulation used in conventional breeding should be excluded from assessments. Other matters out of scope include:

- trade and marketability issues;
- cost/benefit considerations;
- comparisons with alternative technologies;

- intellectual property; and
- human cloning.

This led to the object of the *Gene Technology Act 2000* (the Act) being defined as: 'to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs'.

The *Gene Technology Act 2000*, which received Royal Assent on 21 December 2000, represents the Commonwealth's component of the national regulatory system. The Act, agreed by the Commonwealth, States and Territories, provides a clearly articulated, coherent system of extensive scientific assessment, built-in consultation processes, monitoring and review mechanisms and stipulates penalties for non-compliance. Since its inception, the Act has provided an efficient and effective system to assess and monitor gene technologies and their applications.

The Gene Technology Regulator

The Act establishes the Gene Technology Regulator as an independent statutory office holder to administer the Act, according to the functions specified in section 27. Numerous people have filled the Regulator position over the last 20 years, including in an acting capacity, with three appointments to the role: Dr Sue Meek, Dr Joe Smith and Dr Raj Bhula. Those that have been in the position for a substantive period are set out in Table 1.

Table 1: The position of the Regulator for substantial period over the last 20 years.

Tenure	Who	Position
January 2001 - December 2001	Elizabeth Cain	Interim Regulator
December 2001 - May 2008	Dr Sue Meek	Regulator
March 2009 - March 2014	Dr Joe Smith	Regulator
July 2016 - current	Dr Raj Bhula	Regulator

The Office of the Gene Technology Regulator

The Act does not establish the OGTR; it is an administrative structure staffed by employees of the Department of Health to support the Regulator in the administration of the Act. The OGTR has essentially maintained its two Branch organisational structure since the early 2000s. The Evaluation Branch provides the scientific and technical capacity to assist the Regulator in authorisations, including preparing risk assessment and management plans. The Regulatory Practice and Compliance Branch has provided regulatory expertise, support functions and monitoring functions. Staffing at the office has also remained relatively constant at between 45-55 people since 2005.

Governance, advisory and consultation structures for the Scheme

The Gene Technology Ministers' Meeting (GTMM; formerly known as Gene Technology Ministerial Council and then the Legislative and Governance Forum on Gene Technology) is the ministerial forum that oversees the National Gene Technology Scheme. Cooperation between the Australian Government and the states and territories for implementation of the scheme is set out in the intergovernmental Gene Technology Agreement 2001 (the Agreement). The scheme comprises the Agreement, the Act, the Gene Technology Regulations 2001 (Cth) (the Regulations), and the corresponding state and territory legislation (Figure 1).

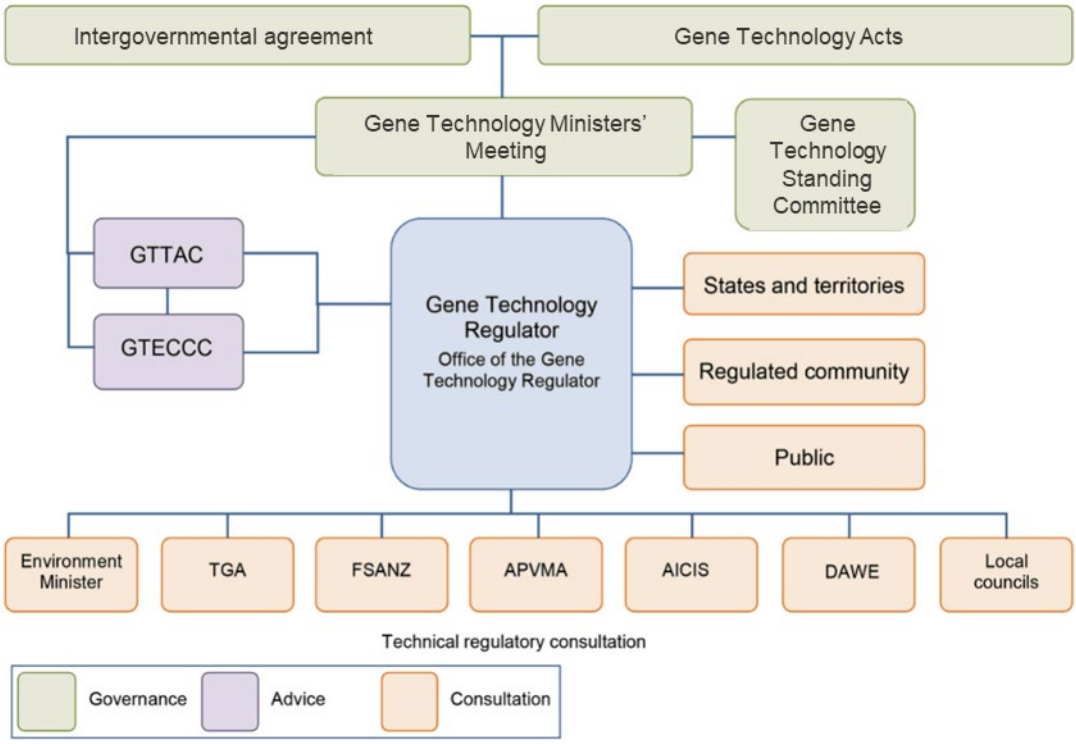

Figure 1: Overview of the regulatory system for gene technology in Australia.

The Act also establishes two advisory committees to provide advice to the Regulator and the GTMM:

- **the Gene Technology Technical Advisory Committee (GTTAC)**: provides scientific and technical advice to the Regulator on matters including: gene technology, GMOs and GM products and applications made under the legislation. Expert scientific and technical guidance from GTTAC assists the Regulator to assess licence applications in an informed manner. GTTAC members come from relevant scientific fields, including agriculture, medical sciences, public health and ecology, as well as risk assessment. A layperson and a GTECCC member also sit on GTTAC. The breadth of knowledge and experience that the committee offers is essential in a complex field like gene technology.
- **the Gene Technology Ethics and Community Consultative Committee (GTECCC)**: Originally, the current functions of GTECCC were performed by two different committees: the Gene Technology Community Consultative Committee (GTCCC) and the Gene Technology Ethics Committee (GTEC). GTCCC provided advice on matters of community concern regarding gene technology to guide the Regulator's decision-making. GTEC provided advice on the ethics of gene technology, appropriate ethics guidelines and any necessary prohibitive directives. These functions were then merged into the one committee following the statutory review of the Act in 2006. The Regulator can consult GTECCC for advice on ethical issues that relate to gene technology and how to manage its challenges. The Act also enables the Regulator and the GTMM to seek advice and information from GTECCC on other matters. Examples include guidance on community consultation, and how best to communicate risk analysis to stakeholders and interested parties.

Committee members are appointed on the basis of their knowledge, skills and experience. As the field of gene technology is a highly specialised area of science, GTTAC and GTECCC members need to have up-to-date expertise relevant to gene technology, and the work of the committees, to perform their roles effectively. This may include having committee members that are currently involved in the diverse research and development fields related to gene technology, including research into, or the development of, GMOs and GM-derived products and applications.

GMOs, dealings and authorisations

The Gene Technology Act 2000 (the Act) defines a GMO as:

(a) an organism that has been modified by gene technology; or

(b) an organism that has inherited particular traits from an organism (the ***initial organism***), being traits that occurred in the initial organism because of gene technology; or

(c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms;

but does not include:

(d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or

(e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.

Section 10 of the Act defines 'deal with', in relation to a GMO, as:

(a) conduct experiments with the GMO;

(b) make, develop, produce or manufacture the GMO;

(c) breed the GMO;

(d) propagate the GMO;

(e) use the GMO in the course of manufacture of a thing that is not the GMO;

(f) grow, raise or culture the GMO;

(g) import the GMO;

(h) transport the GMO;

(i) dispose of the GMO;

and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i).

Different classes of GMO dealings require different types of authorisation, based on risk to the safety and health of Australia's people and environment (Figure 2):

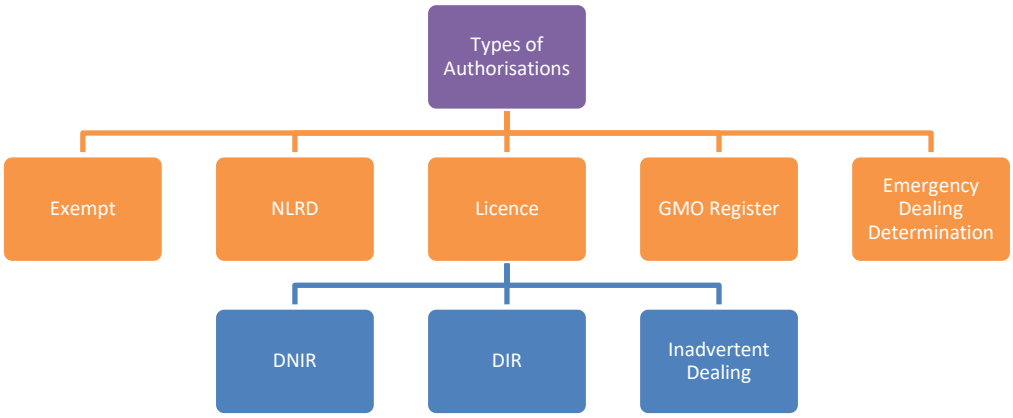

Figure 2: Types of authorisations required for work with GMOs.

- exempt dealings – dealings that pose a very low risk; they must not involve release of the GMO into the environment.
- Notifiable Low Risk Dealings (NLRDs) – dealings that pose a low risk to the health and safety of people and the environment provided that certain risk management conditions are met; they must be conducted in certified containment facilities.
- licenced dealings – dealings that do not meet the criteria for classification as NLRDs or exempt dealings. Measure to manage risks posed by these GMO dealings are required by setting licence conditions that must be followed by anyone undertaking these specified dealings. The three types of licences are:
    - Dealings Not involving Intentional Release (DNIRs) – dealings must not involve release of GMOs into the environment
    - Dealings involving Intentional Release (DIRs) – dealings involve intentional release of GMOs into the environment
    - Inadvertent dealings – to authorise dealings that occur after someone comes into possession of a GMO without intending it, including disposal of the GMO.
- dealings on the GMO Register – dealings that were previously licensed but have now been assessed by the Regulator as being sufficiently safe that they no longer require a licence.
- dealings specified in an Emergency Dealing Determination (EDD) – dealings authorised by the Australian Government minister in an emergency.

The information on all GMOs approved by, or notified to, the Regulator or specified in an Emergency Dealing Determination is contained in the record of GMO dealings (the GMO Record). When the Act first came into effect, the Record included GM product authorisations by other regulators (eg GM food products authorised by Food Standards Australia New Zealand). Following amendments in 2015, the Record has only included GMO dealing authorisations.

How the Regulator assesses licence applications

The Regulator conducts a comprehensive and consultative process to decide whether or not to issue a licence to work with the GMOs. This comprehensive and consultative processes are governed by the Act, the Gene Technology Regulations 2001 (the Regulations) and corresponding state and territory law.

For both DNIRs and DIRs the legislation requires the Regulator to prepare a risk assessment and risk management plan (RARMP) as part of the process of making a decision on whether to issue or refuse a licence (sections 47 and 50 of the Act respectively). The licensing system is centred on a rigorous process of risk assessment based on scientific evidence. The OGTR's Risk Analysis Framework (RAF; OGTR 2013) outlines how the Regulator evaluates licence applications and develops RARMPs (Figure 3). Since the first edition was published in 2002, the RAF has been refined gradually, to reflect 'the evolving nature of the work of the OGTR' (OGTR 2009:iii). The RAF can be used for broader GMO risk analysis as well as in the consideration of GMO licence applications (OGTR 2018:6).

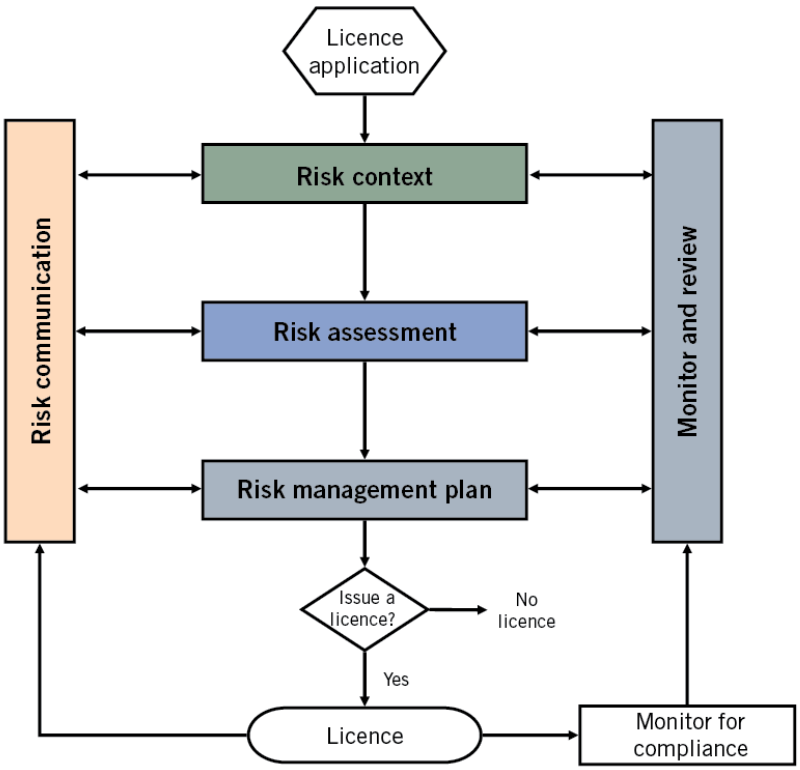

Figure 3: Risk Analysis Framework used by the OGTR when considering a GMO licence application.

For DIRs, the legislation requires consultation with a wide range of experts, agencies and authorities, as well as the public. These include the Gene Technology Technical Advisory Committee (GTTAC), state and territory governments, Australian Government agencies prescribed in the Regulations, the Environment Minister, and relevant local councils. The RARMP is finalised based on the advice received on the licence application and consultation RARMP from the above-mentioned experts, agencies, authorities and the public (Figure 4). The finalised RARMP and licence conditions inform the Regulator's decision on whether to issue or refuse a licence. The Regulator can only issue a licence if satisfied that risks can be managed. If the Regulator does decide to issue a licence, the RARMP informs the conditions that apply to it.

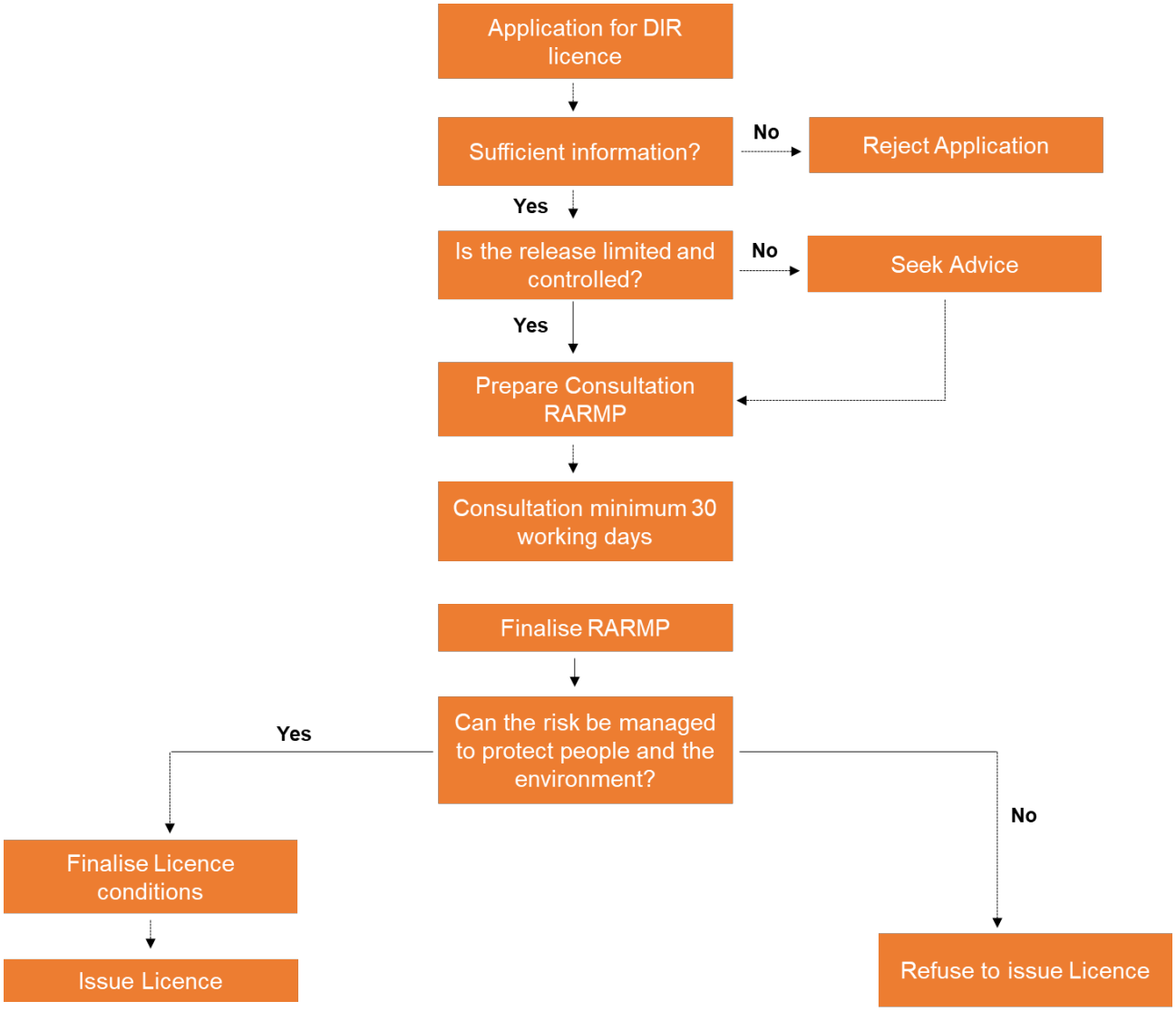

Figure 4: Overview of assessment of a DIR licence process

The Regulator assesses the GMO dealings that may as pose a higher risk to the people and the environment than NLRDs. The process to assess DNIR licence applications is similar to that for DIR licence applications (Figure 5). There is no prescribed consultation process for DNIR applications but at the Regulator's discretion, the Gene Technology Technical Advisory Committee (GTTAC) and State and territory governments can be consulted.

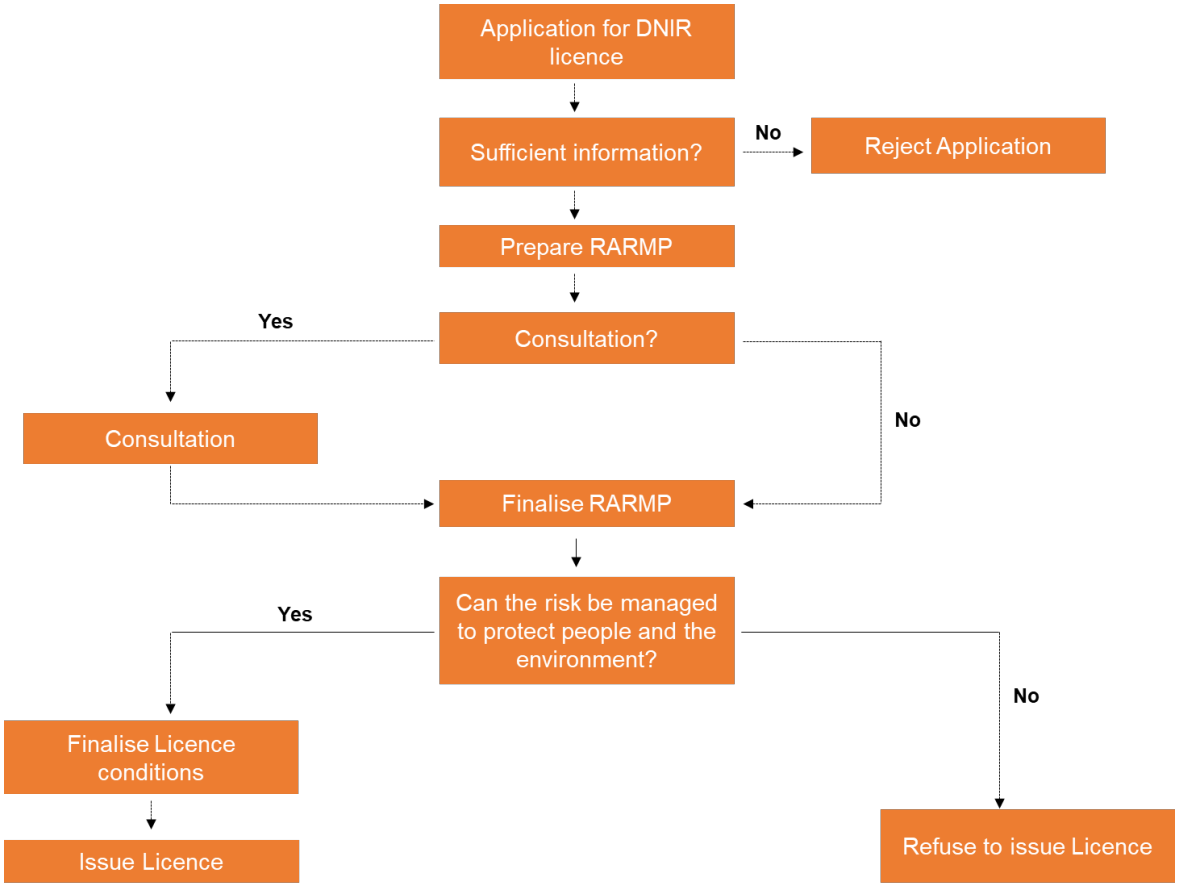

Figure 5: Overview of assessment of a DNIR licence application.

The Regulator evaluates applicants' information in an independent and objective way, and there is a consultation phase for RARMPs prepared for DIR applications. These aspects of the process are strengths of the Australian system and set it apart from some of its international counterparts.

For inadvertent dealings, Part 5 of the Act allows the Regulator to grant a temporary licence (no longer than 12 months) to a person who finds they are inadvertently dealing with an unlicensed GMO, for the purposes of handling and transport for disposal of the GMO.

Inadvertent dealing licences were introduced with the 2007 amendments to the Act and the Regulations as a result of the statutory review of the Scheme. The statutory review identified that there was a need for a mechanism to allow a person who unintentionally has an unapproved GMO on their property, or in their possession, to dispose of the GMO without breaching the Act. An inadvertent licence was granted by the Regulator in 2017 to allow persons to dispose of GM petunia that they had unintentionally received from an overseas supplier. Inadvertent dealings licences for GM petunia are discussed further in Retrospective report 3 and changes to the legislation are discussed further in Retrospective report 4.

Bibliography

Commonwealth of Australia (1992). *Genetic manipulation: the threat or the glory?*, Parliament of Australia, Canberra.

Commonwealth of Australia (2000). *A cautionary tale: fish don't lay tomatoes* – a report on the Gene Technology Bill 2000, Parliament of Australia, Canberra.

Cormick C & Mercer R (2017). *Community attitudes towards gene technology*, Instinct and Reason, Canberra.

Cormick C & Mercer R (2019). *Community attitudes towards gene technology*, Instinct and Reason, Canberra.

DoH (Australian Government Department of Health) (2013). *Operations of the Gene Technology Regulator annual report 2012–13*, DoH, Canberra.

DoH (Australian Government Department of Health) (2014). *Operations of the Gene Technology Regulator annual report 2013–14*, DoH, Canberra.

DoH (Australian Government Department of Health) (2015). *Operations of the Gene Technology Regulator annual report 2014–15*, DoH, Canberra.

DoH (Australian Government Department of Health) (2016). *Operations of the Gene Technology Regulator annual report 2015–16*, DoH, Canberra.

DoH (Australian Government Department of Health) (2017). *Operations of the Gene Technology Regulator annual report 2016–17*, DoH, Canberra.

DoH (Australian Government Department of Health) (2018a). *The third review of the National Gene Technology Scheme*, DoH, Canberra.

DoH (Australian Government Department of Health) (2018b). *Operations of the Gene Technology Regulator annual report 2017–18*, DoH, Canberra.

DoH (Australian Government Department of Health) (2019). *Operations of the Gene Technology Regulator annual report 2018–19*, DoH, Canberra.

DoH (Australian Government Department of Health) (2020). *Operations of the Gene Technology Regulator annual report 2019–20*, DoH, Canberra.

DoHA (Australian Government Department of Health and Ageing) (2002a). *Quarterly report of the Gene Technology Regulator for the period 1 July to 30 September 2002*, DoHA, Canberra.

DoHA (Australian Government Department of Health and Ageing) (2002b). *Quarterly report of the Gene Technology Regulator for the period 1 October to 31 December 2001*, DoHA, Canberra.

DoHA (Australian Government Department of Health and Ageing) (2006). *Operations of the Gene Technology Regulator annual report 2005–06*, DoHA, Canberra.

DoHA (Australian Government Department of Health and Ageing) (2007). *Operations of the Gene Technology Regulator annual report 2006–07*, DoHA, Canberra.

DoHA (Australian Government Department of Health and Ageing) (2009). *Operations of the Gene Technology Regulator annual report 2008–09*, DoHA, Canberra.

DoHA (Australian Government Department of Health and Ageing) (2011). *Operations of the Gene Technology Regulator annual report 2010–11*, DoHA, Canberra.

DoHA (Australian Government Department of Health and Ageing) (2012). *Operations of the Gene Technology Regulator annual report 2011–12*, DoHA, Canberra.

DoHAC (Australian Government Department of Health and Aged Care) (2000). *Interim Office of the Gene Technology Regulator quarterly report June 2000*, DoHAC, Canberra.

GMAC (Genetic Manipulation Advisory Committee) (1998). *Annual report 1997–98*, GMAC, Canberra.

GMAC (Genetic Manipulation Advisory Committee) (1999). *Annual report 1998–99*, GMAC, Canberra.

OGTR (Office of the Gene Technology Regulator) (2013). *Risk Analysis Framework*, Australian Government Department of Health, Canberra.

OGTR (Office of the Gene Technology Regulator) (2009). *Risk Analysis Framework*, Australian Government Department of Health and Ageing, Canberra.

OGTR (Office of the Gene Technology Regulator) (2018). *Monitoring and Compliance Framework*, Australian Government Department of Health, Canberra.

Polya R (2001). *Genetically modified governance issues*, Research Paper 17 2000-01, Parliament of Australia, Canberra.

Shortened forms

DIR	dealing involving intentional release into the environment
DNIR	contained dealing with GMO not involving intentional release into the environment
EDD	emergency dealing determination
GM	genetically modified
GMAC	Genetic Manipulation Advisory Committee
GMO	genetically modified organism
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTMC	Gene Technology Ministerial Council
GTTAC	Gene Technology Technical Advisory Committee
LGFGT	Legislative and Governance Forum on Gene Technology
NLRD	notifiable low risk dealing
OGTR	Office of the Gene Technology Regulator
RAF	Risk Analysis Framework
RARMP	risk assessment and risk management plan
Regulator	Gene Technology Regulator