



Australian Government

Department of Health, Disability and Ageing
Office of the Gene Technology Regulator

COST RECOVERY IMPLEMENTATION STATEMENT

Office of the Gene Technology Regulator (OGTR)

2026-27

Effective: 1 March 2027

Charging for regulatory activity involves government entities charging individuals or organisations in the non-government sector some or all of the minimum efficient costs of a specific government activity. The Cost Recovery Policy along with the Australian Government Charging Framework (the Charging Framework) sets out the policy under which government entities design, implement and review charging for regulatory activities. The Cost Recovery Implementation Statement (CRIS) is the public document to ensure the transparency and accountability for the level of the charging and to demonstrate that the purpose for charging, as decided by Government, is being achieved.

Table of Contents

1. Glossary	4
2. Ownership of Intellectual Property Rights	5
3. Introduction	6
3.1. The Role of the Office of the Gene Technology Regulator (OGTR)	7
3.2. Statutory Authority to Charge	8
3.3. Policy Authority to Cost Recover	9
3.4. History of Cost Recovery Decisions	10
4. Supporting Innovation and Research through Effective and Efficient Cost-Recovery Activities	10
4.1. Continuous Improvement and Process Efficiency Initiatives	11
4.2. OGTR Key Performance Indicators	11
5. ABC and Cost Recovery Methodology	12
6. Design of Cost Recovery	12
6.1. Regulatory charges used	12
6.2. Relationship between charges and costs	13
6.3. Other recoverable activities built into the application fee	13
7. Cost Recovery Model	13
7.1. Licences	13
7.1.1. Background	13
7.1.2. Outputs of OGTR's regulatory charging activities	14
7.1.3. ABC and Cost Recovery Methodology – Licences	15
7.1.4. Design of Cost Recovery – Licence Application Fees	17
7.2. Certifications	18
7.2.1. Background	18
7.2.2. Outputs of OGTR's regulatory charging activities	19
7.2.3. ABC and Cost Recovery Methodology – Certifications	19
7.2.4. Design of Cost Recovery - Certification Application Fees	20
7.3. Annual Charge	21
8. Risk Assessment	22
8.1. Risk Mitigation	24
9. Stakeholder Engagement	24
9.1. Summary of stakeholder engagement undertaken to date	25
9.2. Addressing key stakeholder views	25
9.3. Stakeholder Engagement Plan - 2026/2027	26
9.3.1. Governance Committee	26
9.3.2. Industry Reference Group (IRG)	26
9.3.3. Institutional Biosafety Committee (IBC) Forum	27
10. Consultation Process	27
10.1. Stakeholder Participation	28
10.1.1. Consultation Participation Summary	28

10.2. Key Consultation Themes – Infographic or written	28
10.2.1. Summary of Stakeholder Feedback	28
10.3 Outcomes of Consultation	28
11. Communications Materials	29
12. Financial estimates	29
13. Performance	30
13.1. Financial performance	30
13.2. Non-financial performance	30
14. CRIS approval and change register	31
Appendix A: Appropriateness of Charging for Regulatory Activities	32
Appendix B: Cost associated with each step of licence and certification applications	33

DRAFT

1. Glossary

Acronym	Full name
ABC	Activity Based Costing
AGCF	Australian Government Charging Framework
CCI	Confidential Commercial Information
CRA	Charging Risk Assessment
CRIS	Cost Recovery Implementation Statement
DIR	Dealings Involving intentional Release
DNIR	Dealings Not Involving intentional Release
GM	Genetically Modified
GMOs	Genetically Modified Organisms
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
IRG	Industry Reference Group
NLRD	Notifiable Low Risk Dealing
OGTR	Office of the Gene Technology Regulator
PBS	Portfolio Budget Statement
PC	Physical Containment
RARMP	Risk Assessment and Risk Management Plan
the Act	<i>Gene Technology Act 2000 (Cth)</i>
the Regulations	Gene Technology Regulations 2001 (Cth)
the Regulator	the Gene Technology Regulator
the Scheme	National Gene Technology Scheme

2. Ownership of Intellectual Property Rights

Unless otherwise noted, copyright (and any other intellectual property rights, if any) in this publication is owned by the Commonwealth of Australia (referred to as the Commonwealth).

Creative Commons Licence

All material in this publication is licensed under a Creative Commons Attribution 4.0 International Licence, except for:

- the Commonwealth Coat of Arms
- any logos, emblems and trademarks
- images and photographs
- content supplied by third parties.

The Creative Commons Attribution 4.0 International Licence allows you to copy, communicate, distribute, and adapt this publication, provided you attribute the work appropriately.

A summary of the licence terms is available at [Creative Commons Attribution 4.0 International Licence](#).

This publication (and any material sourced from it) should be attributed as:

Office of the Gene Technology Regulator, Cost Recovery Implementation Statement 2026–27, prepared by the Office of the Gene Technology Regulator, Canberra.

Enquiries regarding copyright, licensing and use of this publication should be directed to:

Office of the Gene Technology Regulator

Email: ogtr@health.gov.au

Telephone: 1800 181 030

Web: www.ogtr.gov.au [\[ogtr.gov.au\]](http://ogtr.gov.au)

For information about contacting the Office of the Gene Technology Regulator, submitting enquiries, providing feedback, or subscribing to updates about gene technology regulation, visit the OGTR's Contact and Subscribe page: [Contact and subscribe | Office of the Gene Technology Regulator](#). [\[ogtr.gov.au\]](http://ogtr.gov.au)

The Australian Government, acting through the Office of the Gene Technology Regulator, has exercised due care and skill in the preparation and compilation of the information contained in this publication. To the maximum extent permitted by law, the Commonwealth disclaims all liability, including liability for negligence, for any loss, damage, injury, expense or cost incurred by any person as a result of accessing, using, or relying upon any of the information contained in this publication.

3. Introduction

Gene technology, also known as genetic engineering or genetic modification, is a growing industry both across the world and in Australia. The practice is a modern branch of biotechnology which allows for the direct modification or removal of a gene from an organism and in some cases, the transplantation of one organism's gene to another.¹

In Australia, research and commercialisation of gene technology is occurring in universities, public and private research organisations, and commercial organisations ranging from small start-ups to large international companies. Gene technology is increasingly common in agricultural practices, medicine and veterinary science and has made important contributions to each industry.²

The Gene Technology Regulator (the Regulator) is an independent statutory office holder responsible for administering Australia's nationally consistent Gene Technology Regulatory Scheme established under the *Gene Technology Act 2000* (the Act) and corresponding State and Territory legislation. The Office of the Gene Technology Regulator (OGTR) supports the Regulator in enacting their administrative responsibilities and delegations. The OGTR is responsible for protecting the health and safety of people and the environment by identifying and managing risks posed by or as a result of gene technology, and by managing that risk through regulating certain dealings with genetically modified organisms (GMOs).³ The regulatory scheme supports innovation in biotechnology while ensuring robust safeguards, effective compliance monitoring and public confidence in the regulation of gene technology in Australia.

The role of the Regulator and the OGTR were created through the passage of the Act and are supported by the National Gene Technology Agreement and subsequent National Gene Technology Scheme (the Scheme), which have been agreed to by all Australian jurisdictions. The OGTR is advised by the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Ethics and Community Consultative Committee.

The gene technology sector has evolved significantly since the commencement of the Gene Technology Scheme in 2001. Advances in agricultural biotechnology, human and veterinary therapeutics, vaccines, gene therapies, synthetic biology and industrial biotechnology have increased both the volume and complexity of regulatory activities undertaken by the OGTR. This growth has driven greater demand for regulatory assessment, compliance, stakeholder engagement and policy support functions across an increasingly diverse and commercially mature sector.

In recognition of these changing demands, the Australian Government provided funding through the 2026–27 Budget to implement a sustainable funding model for the Scheme, including the phased introduction of cost recovery arrangements. The initial phase of cost recovery will utilise existing legislative charging powers and apply to selected regulatory activities, including licence application and facility certification activities. Future phases may expand cost recovery arrangements, subject to legislative change and government decisions.

The Australian Government Charging Framework (AGCF) and Cost Recovery Policy establish the principles that govern how Commonwealth entities design, implement and review cost recovery arrangements. The framework promotes transparency, accountability and consistency in regulatory charging and supports the efficient use of public resources. Under the Australian Government's Charging Policy, where specific individuals, organisations or industries create a demand for a government activity, they should generally bear, at least, the costs of providing that activity unless the government has determined that the activity should be funded by government. This ensures that the costs of regulation are allocated fairly between those who directly benefit from, or drive demand for, regulatory activities and the broader community.

¹ Office of the Gene Technology Regulator (2018), What is gene technology, <<https://www.ogtr.gov.au/resources/publications/what-gene-technology>>

² Office of the Gene Technology Regulator (2018), What is gene technology, <<https://www.ogtr.gov.au/resources/publications/what-gene-technology>>

³ The *Gene Technology Act 2000*

Consistent with the AGCF, fees and charges are designed to recover no more than the costs of delivering regulatory activities. Cost recovery does not seek to generate revenue or profit for government. Rather, it provides a sustainable and equitable funding mechanism that supports the ongoing delivery of effective, risk-based regulation while maintaining appropriate safeguards for innovation, research and commercial development in the gene technology sector. The government has also determined that certain activities, including purely research-based licence applications, will remain exempt from cost recovery as part of its commitment to supporting scientific research and innovation.

This Cost Recovery Implementation Statement (CRIS) sets out how the OGTR will implement cost recovery arrangements for relevant regulatory activities undertaken under the Act and associated legislative instruments. It provides information on the policy and legislative authority for charging, the regulatory activities subject to cost recovery, the methodology used to determine costs and charges, stakeholder engagement activities and financial and non-financial performance information. The CRIS is intended to provide transparency and accountability to regulated entities, stakeholders and the Australian community by demonstrating how cost recovery arrangements are designed and implemented in accordance with the AGCF and cost recovery policy requirements.

3.1. The Role of the Office of the Gene Technology Regulator (OGTR)

The OGTR supports the Regulator in exercising the functions and powers conferred under the Act and corresponding State and Territory legislation. The object of the Act, and correspondingly the role of the Regulator, is 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 that risk through regulating certain dealings with GMOs.⁴

The Regulator performs an important role in ensuring that the development and use of gene technology in Australia occurs within a robust, science-based and risk-proportionate regulatory framework. In achieving this objective, the Regulator has the following functions:

- assessing applications for authorisations involving GMOs and making regulatory decisions
- certifying facilities used for dealings involving GMOs
- accrediting organisations undertaking dealings with GMOs
- monitoring and enforcing compliance with legislative and licence requirements
- developing technical and procedural guidance
- providing information and advice to governments, regulators, stakeholders and the public
- undertaking or commissioning research relating to risk assessment and biosafety
- promoting national and international harmonisation of regulatory approaches to gene technology
- maintaining links with international organisations and overseas regulators involved in gene technology regulation.

The Scheme operates as part of a broader national regulatory system. In exercising its functions, the Regulator collaborates with a range of Australian Government, State and Territory agencies whose regulatory responsibilities intersect with gene technology, including human therapeutics, agricultural products, food, environmental management and biosecurity regulation.

Since the commencement of the Scheme in 2001, the gene technology sector has continued to evolve, with increasing applications in agriculture, medicine, health technologies, industrial biotechnology and research. Developments such as gene editing, advanced therapeutics, synthetic biology and genetically modified (GM) vaccines have contributed to increasing complexity and diversity in regulatory activities. The OGTR continues to adapt its regulatory approach to ensure

⁴ The *Gene Technology Act 2000*

Australia's regulatory framework remains fit for purpose, scientifically robust and responsive to technological advancement.

The OGTR delivers regulatory activities that support the safe use of gene technology while maintaining public confidence in the regulatory system. Through assessment, authorisation, monitoring, compliance, regulatory practice advice and stakeholder engagement activities, the OGTR contributes to protecting human health and the environment while supporting responsible innovation and investment in Australia's gene technology sector.

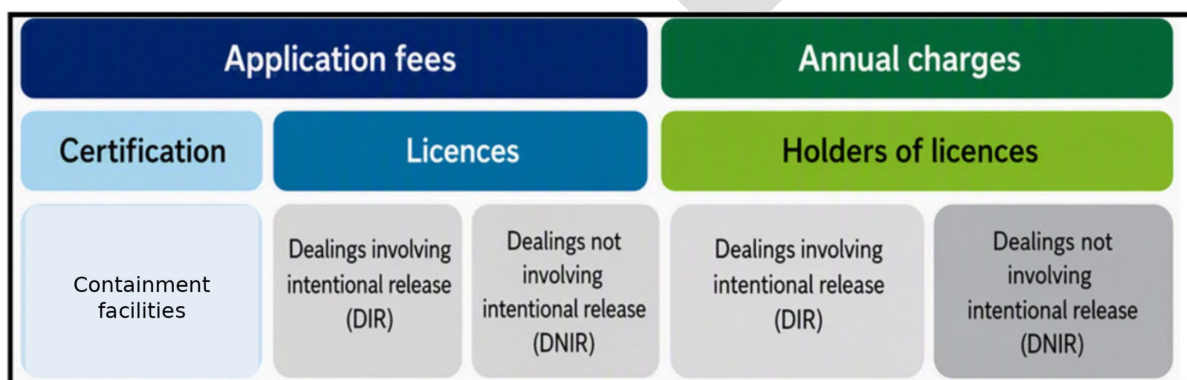
3.2. Statutory Authority to Charge

The Act and the *Gene Technology (Licence Charges) Act 2000* enable the OGTR to charge fees for regulatory functions including application fees for certifications and licences and annual charges for holders of licences. There are currently no fees prescribed in the Gene Technology Regulations 2001 (the Regulations) to cover the regulatory activities undertaken by the OGTR. The scope of fees able to be charged by the OGTR under statutory authority is outlined below (Figure 1).

The statutory authority to charge fees for licence applications is provided in the Act, in section 40(6). The power to charge these fees only extends to Licence dealings. The holder of a GMO licence is also subject to possible annual charges as per the *Gene Technology (Licence Charges) Act 2000*.

The OGTR also has the statutory authority to charge an application fee for certification under section 83(3) of the Act.

Figure 1: Current statutory authority to charge



The OGTR undertakes a range of additional regulatory functions for which it does not currently have the statutory authority to charge fees, including, for example:

- accreditation of an organisation
- variation of an existing licence, certification or accreditation
- transfer of an existing licence or certification
- suspension of an existing licence or certification or lifting the suspension of an existing licence or certification
- surrender of an existing licence, certification or accreditation
- maintaining the GMO register
- processing notifications of notifiable low-risk dealings (NLRDs) and requests to conduct NLRDs in alternative facilities
- applications to declare information as confidential commercial information (CCI) and administrative effort to ensure non-disclosure in relation to information declared as CCI.

Other responsibilities of the OGTR that are outside the scope of the cost recovery arrangements and will continue to be funded through Government appropriation include (but are not limited to):

- providing information and advice to the public about the regulation of gene technology
- monitoring for compliance with the Act
- providing advice to the Gene Technology Ministers' Meeting about the effectiveness of the existing legislative framework that governs gene technology
- promoting the harmonisation of risk assessments of GMOs by regulatory agencies
- monitoring international practices of GMO regulation
- maintaining links with international organisations that regulate gene technology and agencies in other jurisdictions
- maintaining best practice regulation of gene technology in Australia
- maintaining transparency and accountability and supporting the reporting duties of the Secretary of the Department of Health, Disability and Ageing.

3.3. Policy Authority to Cost Recover

In the 2026–27 Budget, the Australian Government approved a sustainable funding model for the OGTR, including the phased introduction of cost recovery arrangements, whilst maintaining support for research and innovation. Cost recovery will be implemented in two phases.

The measure provides:

- \$6.8 million over four years from 2026–27;
- \$1.7 million per year ongoing from 2030–31;
- a phased transition from a fully government funded model to a partial user-pays system.

The Government's decision recognises the maturity of the Australian gene technology sector and supports the long-term sustainability of the Scheme.

Cost recovery will be implemented through:

- Phase 1 (1 March 2027) using existing legislative authority, to introduce charges for licence applications, certification applications and annual licence charges. The cost recovery model recovers the efficient costs associated with regulatory activities undertaken by the OGTR (Table 1). Costs are attributed to activities based on the level of regulatory effort and resources required to assess applications, undertake certification activities and administer licences. These are referred to as regulatory charging activities. Annual charges will also be charged to recover the ongoing costs associated with managing licences. During Phase 1, for licence applications:
 - Commercial applications will be charged at 50 per cent of actual costs.
 - Pre-commercial applications, including clinical trials and field trials, will be charged at 25 per cent of actual costs.
 - Research licence applications will be exempt from licence application fees.

Table 1: Direct and Indirect costs associated with the charge category

Charge Category	Direct Costs	Indirect Costs
Licence	Salary and employee oncosts (superannuation, leave, workers compensation and training)	HR, organisational services, ICT service costs, property operating expense
Certification		

- Phase 2 (anticipated from 1 March 2029) through legislative amendments that expand the range of regulatory activities subject to cost recovery. Application fees will be charged for all application types, not just licence and certification applications, with annual charges applying to other authorisation types. The OGTR will continue to maintain discretion in applying exemptions and exclusions where appropriate and consistent with government policy.

3.4. History of Cost Recovery Decisions

Since its establishment, the OGTR has had the statutory authority through the Act and the *Gene Technology (Licence Charges) Act 2000* to recover costs created by its regulatory activity.

A series of reviews of the Scheme, as well as three focused cost recovery investigations over 25 years have explored the possibility of introducing cost recovery mechanisms. Cost recovery has not previously been implemented given the nature of the emerging gene technology sector in Australia at the time. The size of the sector and the characteristics of its participants (being predominately small and research based) meant that it was anticipated that fees would not generate significant revenue and could limit the ability for smaller market entrants to successfully move from research to commercialisation.⁵

The Third Review of the Scheme, which occurred in 2018, recommended that consideration should be given to the most appropriate funding mechanisms to support the ongoing operation of the scheme.⁶ That review acknowledged that as demand and competition for regulatory oversight in the sector increase, the funding and resources allocated to the OGTR to deliver the regulatory objectives of the Scheme are becoming increasingly dispersed.

4. Supporting Innovation and Research through Effective and Efficient Cost-Recovery Activities

The Australian Government recognises that Australia's gene technology sector is a diverse ecosystem of universities, research institutions, medical facilities, and commercial entities, all of which contribute to scientific advancement, innovation and growth. Cost recovery arrangements have been developed with careful consideration of stakeholder feedback regarding the potential impacts of regulatory charges on research and innovation.

The Australian Government does not intend cost recovery arrangements to discourage research, innovation or the development of new gene technologies in Australia. The phased implementation approach includes targeted exemptions for purely research activities, reduced cost recovery for certain pre-commercial activities and the retention of exemptions and exclusions for organisations with limited capacity to pay.

These arrangements are intended to minimise barriers to research and innovation while ensuring regulatory costs are distributed fairly and proportionately across those who benefit from, or create demand for, regulatory activities.

Through ongoing stakeholder engagement and periodic review, the OGTR will continue to monitor the impacts of cost recovery arrangements to ensure they support regulatory certainty, encourage responsible innovation and maintain Australia's attractiveness as a destination for gene technology research, clinical development, biotechnology investment and advanced manufacturing.

⁵ Commonwealth of Australia (2000) A cautionary tale: Fish don't lay tomatoes – A report on the Gene technology Bill 2000, Chapter 4, <https://www.aph.gov.au/parliamentary_business/committees/senate/community_affairs/completed_inquiries/1999-02/gene/report/index>

⁶ Commonwealth of Australia (2018), The Third Review of the National Gene Technology Scheme, pp. 71-72 <<https://www.genetechnology.gov.au/sites/default/files/2022-02/2017-review-final-report.pdf>> See Recommendation 22.

Cost recovery arrangements will ensure the Scheme can respond effectively to increased demands resulting from fast paced innovation and increasing product delivery in the gene technology sector. Timely, sustainable and responsive regulation provides regulatory certainty to attract industry investment, innovation and productivity.

4.1. Continuous Improvement and Process Efficiency Initiatives

As part of its commitment to efficient and effective regulation, the OGTR commenced a Business Process Mapping Initiative during 2024-25 to document and review its end-to-end regulatory and corporate business processes. The initiative included staff training and capability development in continuous improvement methodologies, to strengthen organisational understanding of process optimisation and value-added activities.

Through a series of process mapping workshops and stakeholder consultations, the OGTR identified opportunities to streamline workflows, reduce manual administrative activities and implement automated solutions where appropriate. These improvements have enhanced operational efficiency, reduced process duplication and strengthened the consistency of regulatory delivery.

The OGTR is committed to embedding a culture of continuous improvement across its operations. Process efficiency initiatives will continue to be reviewed and implemented on an ongoing basis, with any resulting changes incorporated into future activity-based costing and process timing assessments. This approach supports the accuracy of cost recovery charges by ensuring that regulatory costs reflect efficient and contemporary business processes.

4.2. OGTR Key Performance Indicators

To support transparency and accountability, the OGTR intends to publish quarterly performance information following the commencement of cost recovery arrangements. Reporting will include measures of statutory decision-making timeliness, including the percentage of decisions made within legislated timeframes and performance against agreed internal performance indicators (Table 2). These indicators may include targets relating to the proportion of decisions completed within prescribed timeframes or finalised in advance of statutory deadlines.

Table 2: Depicts key performance indicators

KPI	Measure
Timeliness	The PBS* Target of 98% has been met and exceeded with 100% of all licence decisions being made within legislated timeframes.
Processing Efficiency	Reporting of median processing times of: DNIR, DIR Limited & Controlled, Commercial DIR
Transparency	Publish quarterly performance data including median processing times and statutory compliance rates
Continuous Improvement	Monitor and report on statutory clock-stop provisions and processing efficiencies

*Portfolio Budget Statements (PBS) are documents that explain how an entity's funding allocations support the Government's policy priorities and intended outcomes. They provide information on Budget measures, planned expenditure, performance information and the programs and activities the entity will deliver. The PBS help Parliament understand how public resources will be used, what results are expected to be achieved, and how an entity's performance will be monitored and assessed.

5. ABC and Cost Recovery Methodology

The OGTR, with the support of Deloitte Access Economics, adopted an Activity Based Costing (ABC) methodology to determine the efficient costs of regulatory charging activities. The methodology is informed by activity-based data collected since November 2021 from staff directly involved in regulatory assessment, regulatory decision-making and administrative processing activities. This data provides a robust evidence base for identifying the effort and resources required to undertake regulatory functions across the Scheme. The ABC data has been progressively refined to reflect business processes and to provide a consistent and representative approach which strengthens the reliability of the cost recovery model. The proposed charges accurately reflect the regulatory effort required to deliver chargeable activities.

ABC data allocates costs to regulatory activities based on the level of effort and resources required to undertake them. This approach provides a transparent and evidence-based method for identifying the efficient costs of regulatory charging activities while minimising cross-subsidisation between activity types. Only costs attributable to chargeable regulatory activities are recovered through fees and charges. Costs associated with broader regulatory functions, policy development, stakeholder engagement activities and other activities not currently subject to cost recovery continue to be funded through Government appropriation.

Licence application fees are further differentiated by high and low complexity categories, recognising that some applications require significantly greater regulatory effort than others. This approach better aligns fees with costs and reduces the extent to which lower-complexity applications subsidise the assessment of more complex applications.

6. Design of Cost Recovery

6.1. Regulatory charges used

The OGTR proposes to recover the costs of regulatory charging activities through a combination of application fees and annual licence charges. Application fees apply to specific regulatory activities undertaken in response to an application for a licence or certification, while annual licence charges apply to the ongoing administration and management of granted licences (see Appendix A). This charging approach aligns with the AGCF and supports the equitable allocation of regulatory costs to those who create demand for regulatory activities.

Application fees enable the OGTR to recover the efficient costs associated with assessing and processing licence and certification applications as those costs are incurred. This approach provides a direct relationship between the regulatory activity undertaken and the entity requesting the activity. It also helps ensure that charges remain responsive to changes in application volumes and regulatory effort over time.

An annual licence charge is proposed to recover the ongoing regulatory effort associated with administering and managing licences after they have been granted. These activities are not attributable to a single application but are necessary to support the effective operation and integrity of the Scheme. Activities recovered through the annual licence charge include monitoring and auditing, post-authorisation notifications, stakeholder support and enquiries, maintenance of regulatory guidance, information and database management, committee and secretariat functions, and other licence management activities associated with the ongoing administration of licences.

Recovering these costs through an annual licence charge ensures that ongoing licence management activities are funded by licence holders rather than through application fees. This approach aligns the recovery of ongoing regulatory costs with those who continue to hold and benefit from licences and avoids requiring applicants whose applications are unsuccessful to contribute towards activities from which they do not benefit.

6.2. Relationship between charges and costs

The proposed fee amounts are set at levels which fully recover the OGTR's recoverable costs, using the averages of the OGTR's sample dataset. The proposed fee charges aspire to balance the cost variances within and between cost recoverable activities, with the administrative burden on the OGTR of administering the fees and the certainty of fixed fee levels for regulated entities.

6.3. Other recoverable activities built into the application fee

The proposed fees would also recover the proportion of indirect costs which – although incurred as part of the OGTR's overall activities – are attributable in part to the assessment of licence and certification applications, and the management of these applications. These costs include a proportion of payment processing and invoicing to the amount of \$44.90 per invoice.

7. Cost Recovery Model

The charging rates for Phase 1 of cost recovery arrangements are demonstrated below (Table 3).

Table 3: Phase 1 cost recovery arrangements

Charge Category	Commercial	Pre-commercial	Research
Licence Applications	50%	25%	Exempt
Certification Applications	100%	100%	100%
Annual Licence Charge	100%	100%	100%

7.1. Licences

7.1.1. Background

The OGTR issues licences to research organisations and companies who propose to work with gene technology. It is illegal to deal with GMOs in Australia without a licence unless it is an exempt dealing, a NLRD, included on the GMO Register, or an emergency dealing determination.

The OGTR issues several different types of licences, including:

- dealings involving intentional release (DIR) of a GMO
- dealings not involving intentional release (DNIR) of a GMO
- inadvertent dealings.⁷

The two types of licensing of concern in this report are the DIR and DNIR licences. DIR licences are for work with GMOs that are not contained within a facility. This category includes GM crops grown in a field (either commercially or experimentally), GM therapeutics and vaccines tested in a clinical trial, and GM therapeutics and vaccines for sale in a pharmacy or chemist.

DNIR licences are for research or other work contained within a building or other structure (such as in a hospital), rather than outside special facilities. These facilities must be certified by the Regulator as suitable for containing work with GMOs. Other DNIR licences are for activities where the GMO may be contained within a person, such as administration of a GM therapeutic or vaccine that will not be released into the environment. The process for a licence application is outlined below (Figure 2).

⁷ A licence for inadvertent dealings is to authorize the safe disposal of a GMO to a person who has come into possession of the GMO inadvertently.

Figure 2: OGTR licence application process



Source: Deloitte Access Economics

7.1.2. Outputs of OGTR's regulatory charging activities

The volumes of each type of licence application received by the OGTR in the financial years from 2021-22 to 2025-26 are shown below (Table 4).

Table 4: Volume of licence applications received by the OGTR

	2021-22	2022-23	2023-24	2024-25	2025-26
DIR	8	6	7	13	6
DNIR	8	23	25	32	25

Source: Office of the Gene Technology Regulator – Annual report (as published on [OGTR website](#)).

7.1.2.1. Licence application review and assessment process

The process for the OGTR's review and assessment processes for DIR and DNIR licences are broadly similar and are captured below (Table 5).

Table 5: Process for review and assessment of licence applications

Process step	Activities
1. Completeness review and database entry	- review of application for completeness - entry of the information contained in the application into the OGTR's database
2. Suitability review	- review of prospective licence-holder's suitability for holding a licence - DIR licences: Initial Review and Decision. This involves the Regulator considering the application whether it can proceed to the next stage of the assessment process, including notification of receipt of the application on the OGTR website. For commercial releases, the Regulator is required to undertake an expert consultation process.
3. Consultation (DIR licence applications)	- preparation of a summary of the application - undertaking of consultation phase (if the release is not limited and controlled) - public notification (mailout and website publication of the application summary)
4. Risk assessment and draft licence conditions	- drafting of Risk Assessment and Risk Management Plan (RARMP) - DIR licences: Review of the draft RARMP – This involves the Regulator considering the draft RARMP and determining whether it should proceed to public and expert consultation.
5. Consultation phase (DIR licence applications)	- public notification (website, newspaper and gazette publication, mailout) - undertaking of consultation phase
6. Final review and decision	preparation of final RARMP and licence conditions

Process step	Activities
	- final regulatory decision. This involves the Regulator reviewing the final risk assessment and proposed licence conditions and deciding whether to grant a licence.
7. Applicant and public notifications	- notification of application outcome to applicant - notification of application outcome to the public (via website publication) - update of OGTR database to reflect outcome of application

Note: The OGTR may seek additional information from the applicant prior to process step six to inform its assessment but is required to do so at step one if the application is incomplete.

Source: Office of the Gene Technology Regulator.

7.1.2.2. Variability in licence application processes

There are some important variabilities within and between licence application processes which impact the level of effort required to undertake them. For commercial DIR licence applications, two statutory consultations are always required:

- one round of consultation with the states and territories, GTTAC, agencies prescribed in the Regulations, and the Environment Minister on the preparation of the RARMP (captured at step three); and
- one round of consultation with the same bodies as the first round plus the public on the draft RARMP (step five).

For limited and controlled DIR licence applications, one consultation is always required with state and territories, GTTAC, prescribed agencies under the Regulations, the Environment Minister and the public on the draft RARMP.

For DNIR licence applications, the Regulator may consult the states, GTTAC and prescribed agencies at their discretion. If the consultation process is undertaken, it is most often done for applications involving high level containment/high risk pathogens, novel technologies or unusual risks.

The number of consultation rounds required according to the licence application type and the type of proposed activity is captured below (Table 6).

Table 6: Number of consultation rounds required according to licence application type and type of proposed activity

	DIR	DNIR
Commercial activities	2	
Limited and controlled release activities	1	Consultation at Regulator's discretion

Source: Office of the Gene Technology Regulator.

7.1.3. ABC and Cost Recovery Methodology – Licences

Under Phase 1, cost recovery arrangements will apply to licence applications submitted under the Act, while maintaining Government support for research and innovation.

Licence application fees have been designed to reflect both the complexity of the application and the purpose of the proposed activities. Applications will be categorised according to the type of regulatory assessment required and whether the proposed activities are research, pre-commercial or commercial in nature. This approach provides a more proportionate charging framework that better reflects regulatory effort and stakeholder capacity to pay, as well as minimising cross-subsidisation.

Consistent with Government approval:

- licence applications for purely research activities will be exempt from application fees
- pre-commercial activities, will be charged at 25 per cent of the full cost of assessment
- commercial activities will be charged at 50 per cent of the full cost of assessment.

7.1.3.1. DIR

The fee structure for licence applications has been informed by ABC data analysis undertaken by Deloitte Access Economics using OGTR regulatory activity data. The analysis was further expanded by the OGTR. ABC data for a sample of 26 DIR licence applications involved 5 high complexity applications and 21 low complexity applications assessed between November 2021 and June 2026. The average cost of the process steps in the sample of DIR licence applications is presented in Appendix B Table 15.

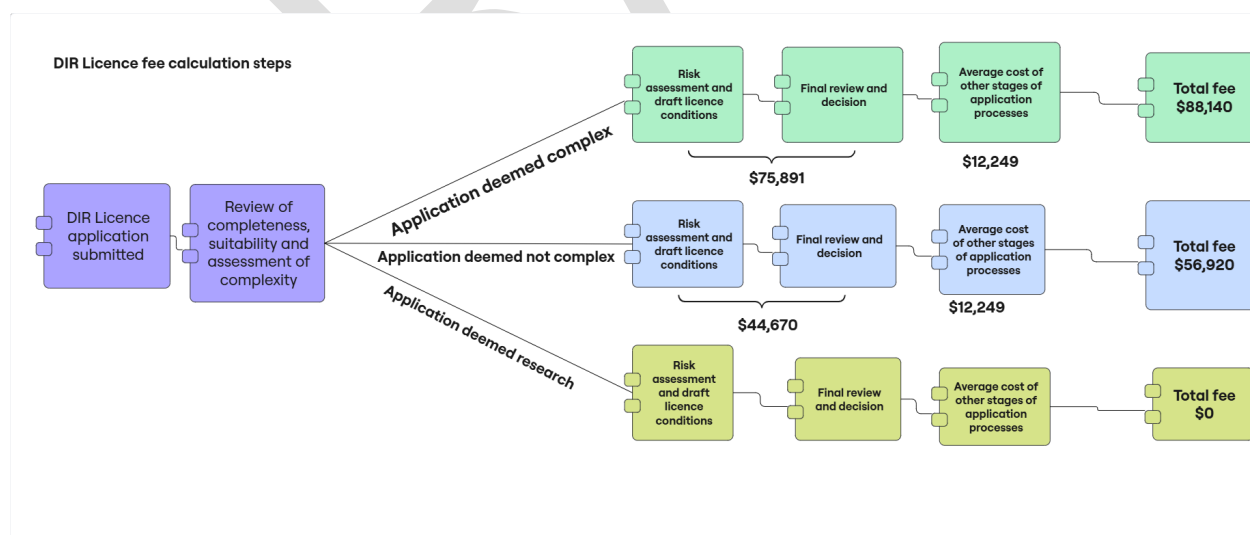
The primary cost drivers of the DIR average total cost are the risk assessment and drafting of licence conditions, representing around 51 per cent of the total cost and the final review and decision representing around 30 per cent of the total cost (Figure 3).

The variability in costs is primarily driven by the following steps:

- time required to prepare the draft RARMP and draft licence conditions
- time required to review submissions in response to public consultation
- time for making amendments to the final RARMP for publication
- changes to draft licence conditions and
- the final decision by the Regulator.

The variability in these steps is influenced by the complexity associated with the analysis and assessment of the prospective risks posed by each applicant's proposed activities. The level of complexity in assessment is influenced by factors such as the novelty of the GMO and the proposed activity, the complexity of the risk assessment required, and whether similar activities have previously been assessed and authorised by the OGTR.

Figure 3: Fee calculation steps for a DIR licence

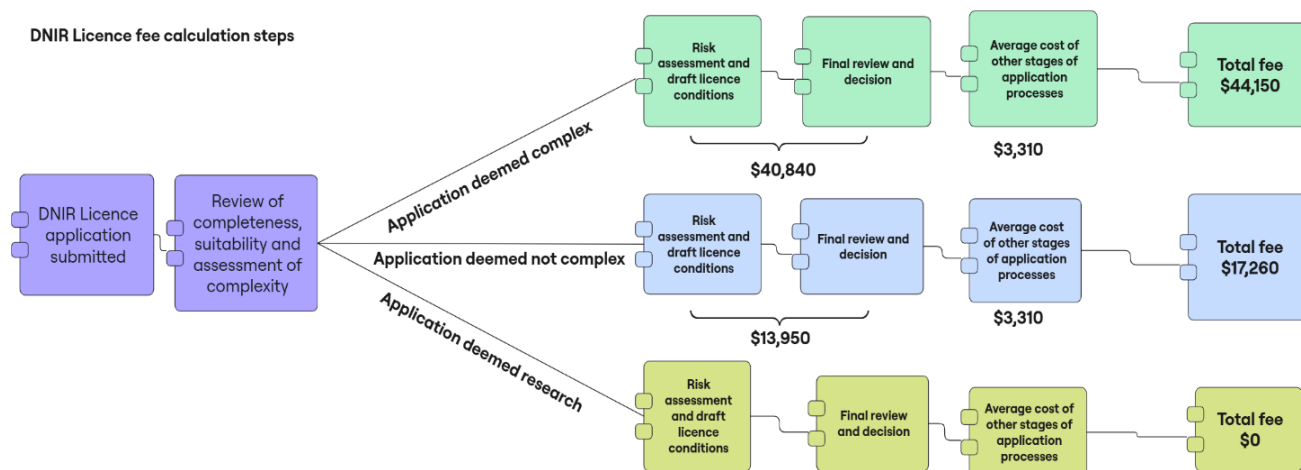


7.1.3.2. DNIR

ABC data for a sample of 88 DNIR licence applications assessed between September 2022 and June 2026 were considered. This involved 6 high complexity applications and 82 low complexity applications. The average cost of the process steps in the sample of DNIR licence applications is presented in Appendix B Table 16.

As with DIR licences, the primary cost drivers of the DNIR average total cost are the risk assessment and drafting of licence conditions representing around 70 per cent of the total cost, and the final review and decision representing around 12 per cent of the total cost. As with the DIR steps above, expert consultation if required adds time to the RARMP preparation (Figure 4).

Figure 4: Fee calculation steps for a DNIR licence



7.1.4. Design of Cost Recovery – Licence Application Fees

Licence application fees are designed to reflect the efficient regulatory effort required to assess an application. Applications are classified according to their complexity, informed by ABC data, historical assessment effort and expert review. Complexity classifications reflect factors such as the novelty of the activity, risk assessment requirements and consultation needs as set out in the Act and previous assessment history. This ensures charges are aligned with regulatory effort and minimises cross-subsidisation between lower and higher complexity applications. Applications are also classified as research, pre-commercial or commercial, with charges applied in accordance with Government policy settings for Phase 1 cost recovery arrangements (Table 7).

Commercial activities are generally those undertaken for marketing, commercial production, manufacturing, supply or widespread distribution.

Pre-commercial scale activities generally include clinical trial applications (including Phase 1 clinical trials) and agricultural field trials that are of scale.

Research activities generally include proof-of-concept, experimental or exploratory work undertaken primarily for research purposes. Most limited and controlled DIR release applications are expected to fall within the pre-commercial category. However, some early-stage proof-of-concept or experimental activities may be classified as research activities at the discretion of the Regulator.

The charges are based on licence activities and not the type of organisation applying, therefore, it's possible that all organisational types (including those that are research organisations) could pay licence application fees.

The final classification of an application remains a matter for determination by the Regulator, having regard to the nature, purpose and intended outcomes of the proposed activity.

Table 7: Costs and proposed charges for licences

Charge Category	Complexity	Full Cost (\$)	Estimated Volume	Phase 1 Approved Charging Rate	Phase 1 Charge (\$)	Estimated Revenue (\$)
DIR Licence	High	\$88,140				
			1	Commercial (50%)	\$44,070	\$44,070
			1	Pre-commercial (25%)	\$22,030	\$22,030
			0	Research (0%)	\$0	\$0
DIR Licence	Low	\$56,920				
			2	Commercial (50%)	\$28,460	\$56,920
			2	Pre-commercial (25%)	\$14,230	\$28,460
			2	Research (0%)	\$0	\$0
DNIR Licence	High	\$44,150				
			1	Commercial (50%)	\$22,080	\$22,080
			2	Pre-commercial (25%)	\$11,040	\$22,080
			3	Research (0%)	\$0	\$0
DNIR Licence	Low	\$17,260				
			2	Commercial (50%)	\$8,630	\$17,260
			6	Pre-commercial (25%)	\$4,320	\$25,920
			10	Research (0%)	\$0	\$0

All fee levels include an invoicing fee of \$44.90

7.2. Certifications

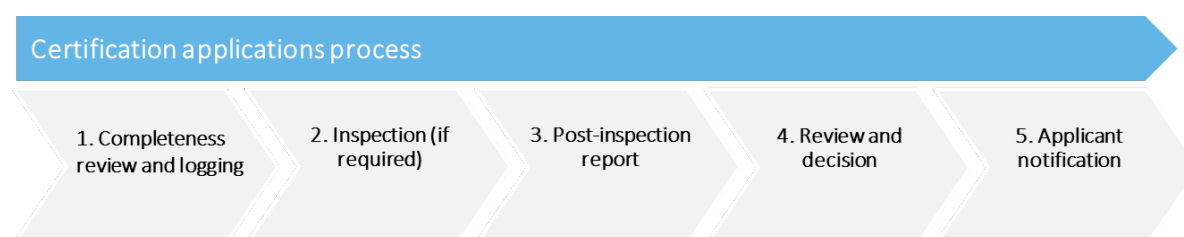
7.2.1. Background

As part of their regulatory activities the OGTR certifies facilities that contain research and manufacturing of GMOs. The certification process verifies that these facilities meet the requirements set out in the [Guidelines for the certification of physical containment facilities](#) before research and manufacturing can take place.

Certifications are issued based on the Physical Containment (PC) level of the facility. Each facility is given a PC level based on the protections and containment types that the facility uses to prevent the GMO from being unintentionally released.

The PC level of a facility reflects the risk level of the type of GMOs within that facility. There are currently four different PC levels: PC1, PC2, PC3 and PC4. The first and second of which are for low-risk GMOs. The latter two are for higher risk GMOs and so involve higher standards for containment protocols. PC4 facilities, for example, must have airlocked entry and exits which include changerooms and a shower. PC3 facilities, whilst including an airlock at entries do not require the inclusion of changerooms or a shower. OGTR has published guidelines with the criteria for each PC type and subtype. The process for facility certification is below (Figure 5).

Figure 5: OGTR facility certification application process



Source: Deloitte Access Economics

Certification application fees will recover the efficient costs of assessing certification applications and vary according to the level of the facility being certified.

7.2.2. Outputs of OGTR's regulatory charging activities

Facilities may be certified by the Regulator to specific containment levels under section 84 of the Act. Physical containment facilities are classified according to the stringency of measures for containing GMOs, and the type of organisms they are intended to contain.

For the purposes of estimating fee revenue and application volumes, the OGTR expects to receive approximately 400 low-level certification applications each year. This estimate is based on historical certification activity and assumes that applications previously processed as certification variations to extend the period of the certification will, where required, be submitted as new certification applications under the Phase 1 charging arrangements. The estimate is intended to provide a reasonable basis for forecasting and will be reviewed as part of future CRIS updates.

7.2.2.1. Certification application review and assessment process

The process for the OGTR's review and assessment of certification applications is captured below (Table 8).

Table 8: Process for review and assessment of certification applications

Process step	Activities
1. Completeness review and database entry	- review of application for completeness - entry of the information contained in the application into the OGTR's database
2. Facility inspection (if required)	- physical inspection of the facility for compliance with the relevant certification guidelines - post-inspection communication with applicant - preparation of post-inspection report
3. Draft certification instrument prepared	preparation of proposed certification instrument
4. Review and decision	review and decision. This asks the Regulator to review the post-inspection report (if applicable) and the proposed certification and decide whether to issue the certification.
5. Applicant notification	- notification of application outcome to applicant - if successful: provision of certification to applicant via email or post

Source: Office of the Gene Technology Regulator.

7.2.3. ABC and Cost Recovery Methodology – Certifications

As part of the Australian Government's approved phased approach to cost recovery, application fees will also apply to facility certification activities undertaken under the Act. Facility certification is a key regulatory activity that supports the safe conduct of dealings involving GMOs by ensuring facilities meet the physical containment requirements appropriate to the work being undertaken.

Unlike licence applications, certification application fees are not differentiated according to whether the proposed activities are research, pre-commercial or commercial in nature. The Government has approved full cost recovery for certification applications, reflecting the relatively lower cost of assessment and the direct relationship between the certification activity and the applicant seeking approval.

To better align charges with regulatory effort, certification applications will be grouped according to the level (high and low-level containment) of the facility being certified. The certification assessment process for high-level containment facilities generally involves greater regulatory effort, including more detailed technical assessment and inspection activities. As a result, separate fee categories will apply for low-level and high-level containment certification applications.

For Phase 1 of cost recovery:

- Low level containment certification applications (generally PC1 and standard PC2 facilities) will be charged at 100 per cent of the recoverable assessment cost
- High level containment certification applications (including large-scale PC2 facilities and PC3 and PC4 facilities) will be charged at 100 per cent of the recoverable assessment cost.

7.2.3.1. High-level certifications

The OGTR defines 'high-level certification' applications as large-scale PC2 applications, and all PC3 and PC4 applications.

For the purposes of cost recovery under Phase 1, high-level containment certification applications will include large-scale PC2 facilities and all PC3 and PC4 facilities.

ABC data for a sample of 44 high-level containment certification applications between July 2022 and June 2026 was reviewed. The analysis was used to determine the efficient regulatory effort associated with assessing high-level containment- facilities. The average cost of a high-level containment certification assessment was \$5,378.

While the OGTR does not have the statutory authority to recover costs associated with variations to existing certifications, the data on variations was recorded and reported as the process associated with a variation to extend a certification is very similar to the process for a new certification application.

The primary cost drivers of the high-level containment certification average total cost are the physical inspection of the containment facility (step three representing 48 per cent of the total cost), and the post-inspection report and drafting of the certification instrument (step four, representing 42 per cent of the total cost) (Appendix B Table 11).

7.2.3.2. Low-level certifications

The OGTR defines 'low-level certification' applications as all PC2 applications except for large scale, and all PC1 applications.

For the purposes of cost recovery under Phase 1, low-level containment- certification applications include all PC1 facilities and standard PC2 facilities.

ABC data for a sample of 68 low-level containment certification applications between August 2022 and September 2024 was reviewed. The total average cost of the sample of low-level containment certification applications was \$116 (Appendix B Table 12). This reinforces the OGTR's advice that the process for assessing and reviewing low-level containment certifications is short and simple, so the variability in process steps for low-level containment certifications do not suggest significant variability in total effort.

7.2.4. Design of Cost Recovery - Certification Application Fees

As the total cost associated with each high-level containment certification application is relatively low, the costs of each process step were averaged to provide a single fee level (Figure 6 and Table 9). The costs of each process step for low-level containment certification applications were also averaged to provide a single fee level.

Figure 6: Fee calculation for certifications

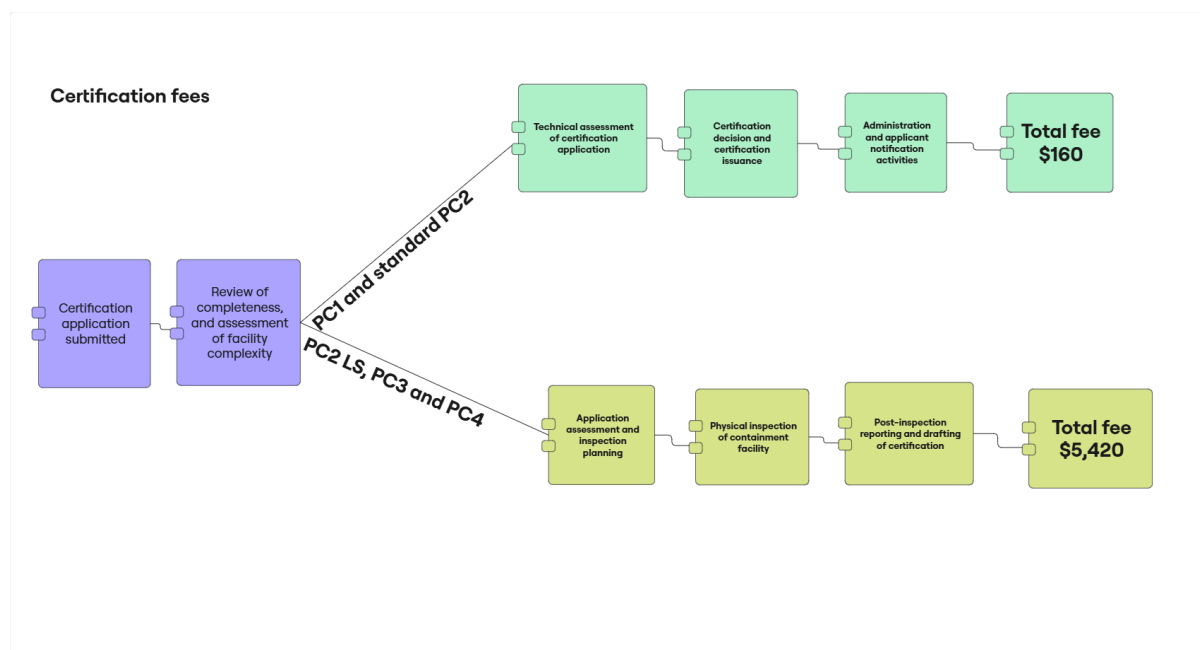


Table 9: Costs and proposed charges for certifications

Charge Category	Containment	Full Cost (\$)	Estimated Volume	Phase 1 Approved Charging Rate	Phase 1 Charge (\$)	Estimated Revenue (\$)
Certification	High level	\$5,420	2	Large scale PC2, PC3, PC4	\$5,420	\$10,840
Certification	Low level	\$160	400	PC1, PC2	\$160	\$64,000

All fee levels include an invoicing fee of \$44.90.

7.3. Annual Charge

The annual licence charge recovers a portion of the ongoing regulatory activities required to administer and maintain the Scheme after a licence has been granted. These activities are not directly attributable to a specific application and therefore are not recovered through application fees. Instead, they are recovered through an annual charge applied to licence holders.

The total costs associated with the regulatory activities outlined were equally apportioned to each licence holder to generate a single annual charge. Each valid and current licence, including research licences, will be charged 100 per cent of the annual charge.

Costs are allocated to regulatory activities based on the effort and resources required to undertake those activities. Activities attributable to the ongoing management and oversight of licence holders are included in the annual licence charge. These include activities such as:

- A) Monitoring and auditing including post authorisation notifications
 - B) Stakeholder support & inquiries
 - C) Maintenance of regulatory guidance
 - D) Database and information management including licence application portal
 - E) Committee and secretariat functions
 - F) Other regulatory activities that contribute to the effective administration of the Scheme
- Ongoing regulatory administration and support activities, including maintenance of standard

operating procedures, quality assurance activities and continuous improvement initiatives associated with licence management.

10% of total OGTR budgets are attributable to licence holders for the above regulatory activities of the office.

Following identification of licence management costs, the total recoverable annual costs attributable to licence management activities are aggregated and apportioned equally across licence holders to generate a single annual licence charge (Table 10). This approach minimises administrative complexity during the initial phase of implementation and provides licence holders with certainty regarding annual charges.

Many of these activities support multiple authorisation types across the Scheme, including certifications, accreditations and notifications. Accordingly, only the proportion of costs attributable to licence holders is recovered through the annual licence charge.

Table 10: Proposed annual licence charge

Charge Category	Full Cost (\$)	Estimated Volume	Phase 1 Charge (\$)	Estimated Revenue (\$)
Annual licence charges	\$3,710	247	\$3,710	\$916,370

All fee levels include an invoicing fee of \$44.90

8. Risk Assessment

A Charging Risk Assessment (CRA) is undertaken when preparing a new policy proposal for a new regulatory charging activity.⁸ The CRA processes assess implementation risks based on the complexity, materiality and sensitivity of the future operating environment. This includes:

- the extent of changes to cost recovery revenue or whether cost recovery is new
- total proposed annual cost recovery revenue for the activity
- type of cost recovery charges used
- legislative requirements necessary for imposition of cost recovery charges
- need collaboration with other government entities
- impact of cost recovery on payers
- extent of issues raised by stakeholders during consultation.

A preliminary CRA has been included in this Report to outline potential future risks associated with the implementation of new fees being introduced by the OGTR for licences and certifications (Table 11). Three “high risk” responses are required to obtain a “high risk” rating. As shown below, three of the implementation risks associated with the proposed fee model are likely to be considered high-risk. For that reason, the overall risk rating is **high**. The assigned risk rating acknowledges the introduction of fees for the first time and the variability in stakeholders’ financial ability to pay. In particular, there is a risk that if stakeholders are unable to meet these fees, this may deter innovation.

Table 11: Charging Risk Assessment for new OGTR licence and application fees

Implementation risks	Low	Medium	High	Rationale
1. What is the proposed change in annual cost recovery	☐ <5%	☐ 5 < 10 %	☒ >10% Or New	The proposed fees are new.

⁸ Australian Department of Finance, *Better Practice Template for a Charging Risk Assessment (CRA) for regulatory activities*

Implementation risks	Low	Medium	High	Rationale
revenue for the activity?				
2. What is the total proposed annual cost recovery revenue for the activity?	X 0 - \$10m	☐ \$10m < \$20m	☐ \$20m+	The proposed fees are expected to yield approximately \$1.5 million (on average, over five years) in annual cost recovery revenue.
3. What does the policy proposal or change in the cost recovered activity involve?	☐ Change in the level of existing cost recovery charges	☐ Change in the structure of existing cost recovery charges and/or composition of payers	X Introduction of cost recovery for a new activity or for an existing activity (or its components) that has not been cost recovered previously	The proposed cost recovery model involves the introduction of fees for the first time for existing activities that have not been cost recovered previously.
4. What type of cost recovery charges will be used?	☐ Levies only	X Fees only or fees and levies	☐ Fees, levies and other charges	Only application and annual fees are being proposed.
5. What legislative requirements are necessary for imposition of cost recovery charges?	X Does not involve an Act of Parliament (e.g., Regulations, Determinations etc)	☐ Involves an Act of Parliament (e.g., enabling Act or levy imposition Act)	☐ Requires State/Territory legislative changes or referral of powers to the Commonwealth	The proposed fees have been designed based on the OGTR's current statutory authority to charge.
6. Does the proposal involve working with other Commonwealth, State/Territory and/or local government entities?	X No	☐ Yes – with Commonwealth entities only	☐ Yes – with Commonwealth and State/Territory entities	The introduction of fees does not involve working with other levels of government.
7. What will be the expected impact of cost recovery on payers?	☐ Low	X Medium	☐ High	The impact associated with introducing fees varies based on the size of the organisation and the type of activities the organisation conducts. <i>This may depend on, among other things:</i> • the change in the level of charges • the number of people affected • the cumulative effect from other government charges/regulation For large commercial organisations, the impact of introducing fees will be low. However, small organisations as well as organisations who primarily undertake research are more likely to experience disproportionate impacts.

Implementation risks	Low	Medium	High	Rationale
the economic conditions etc.				If the sector is unable to pay, there is a risk that the introduction of fees may deter innovation. The introduction of modular fees based on complexity attempts to better align fees with the sectors ability to pay.
8. What consultation has occurred with payers and other stakeholders about the proposed cost recovery?	☐ Consulted – no significant issues raised	☐ Consulted – significant issues raised but can be addressed	X Not consulted or consulted and significant issues raised but ongoing sensitivities	The cost recovery model outlined in this report has not been tested with stakeholders. This model aims to address previous feedback provided by the sector in response to other options for cost recovery models
Overall CRA Rating	☐ LOW	☐ MEDIUM	X HIGH	

Source: Deloitte Access Economics

8.1. Risk Mitigation

Risks associated with the implementation of the new fees for licence and certifications and their mitigation strategies are outlined below (Table 12).

Table 12: Risks and mitigation strategies

Risk	Description	Mitigation strategy
Deviation from assumptions made regarding the effort associated with processing applications	This risk arises from the fact that the assumptions made regarding the effort associated with processing each application is based on historical data and may vary in future based on changes in complexity, regulations and/or technology. This can lead to over- or under-recovery of costs.	The OGTR will regularly review the assumptions underpinning regulatory effort and activity costs associated with charging activities. This includes monitoring changes in application complexity, operational processes and resource requirements to ensure charges continue to reflect the efficient cost of regulation.
Variance in the number of applications received each year	As above, this risk arises because the assumptions made regarding the quantity of applications received each year are based on historical trends in application submissions. These may not reflect future trends, and this could lead to financial implications including over- or under-recovery of costs.	As above, the OGTR will regularly monitor and review the volume of applications. This can be done by comparing the actual number of applications against the projected figures. If there is a significant difference, it may be necessary to revise the assumptions and adjust the cost model accordingly.

9. Stakeholder Engagement

This chapter discusses previous, current and ongoing engagement and communication pathways with stakeholders as part of cost-recovery development and implementation.

9.1. Summary of stakeholder engagement undertaken to date

The OGTR has undertaken stakeholder consultation over past years to inform the development of cost recovery arrangements for regulatory activities delivered under the Scheme. Initial engagement commenced in 2022 to better understand stakeholder perspectives on the introduction of cost recovery and the potential impacts on regulated entities across the gene technology sector.

Feedback received through this engagement highlighted the diversity of the sector and the varying capacity of organisations to absorb additional regulatory costs. Stakeholders raised concerns regarding affordability, particularly for research organisations, universities and smaller organisations, and the potential impacts that cost recovery arrangements could have on innovation and research activities. At that time, stakeholders also indicated that further consultation on more detailed charging models would be beneficial to better understand how different cost recovery approaches might operate in practice.

To inform the development of a potential charging framework, the OGTR subsequently consulted stakeholders on a range of cost recovery options. These options explored different approaches to allocating costs between commercial and non-commercial activities and sought feedback on issues such as affordability, potential unintended consequences, administrative complexity, perceived value of regulatory services and ease of implementation.

Consultation was undertaken with a broad cross-section of stakeholders, including government agencies, commercial biotechnology organisations, small and medium enterprises, universities, research institutes, hospitals and other regulated entities. Stakeholders were invited to provide feedback through surveys, interviews, focus groups and written submissions. This engagement provided valuable insights into stakeholder priorities, implementation considerations and potential risks associated with introducing cost recovery.

The feedback received through these consultation activities has informed the development of the cost recovery model outlined in this CRIS, including consideration of stakeholder capacity to pay, implementation risks and the need to support ongoing research and innovation within the Australian gene technology sector.

9.2. Addressing key stakeholder views

Previous stakeholder feedback highlighted a need for greater granularity within the fee structure. Stakeholders expressed that the simplicity of the options tested did not align with the complexity of the industry. Many of the research-focused stakeholders found it difficult to classify their activities solely based on commerciality, as research activities have the potential to transition into commercial ventures in the future.

Demand for further granularity was driven by concerns about stakeholder's ability to pay and the significant impact fees could have on their operations. While some stakeholders indicated a reasonably high ability to pay fees for certification applications, their ability to pay for licence applications was much lower.

There was also significant variability in stakeholder's assessment of their ability to pay across the types of organisations within the sector. Small and medium-sized enterprises had varying views on their ability to pay, with some considering even small fees as having a significant impact. Large corporates, on the other hand, felt relatively confident in their ability to pay. Organisations reliant on grants raised concerns about the potential impact of fees on grant availability, with the possibility of the burden falling on the organisations and researchers themselves.

As a result, stakeholders foresaw unintended consequences associated with the introduction of licence application fees. The primary concern was that the introduction of fees may stifle innovation and research in Australia's gene technology industry.

In the new proposed fee structure, further granularity has been added to meet some of these concerns including the purpose of the activities (research, pre-commercial and commercial) and the

complexity of the application itself to better reflect the regulatory effort associated with assessment activities and how the effort may vary between application type

For licences, it is proposed that each application submitted to the OGTR undergo assessment to determine its complexity level and whether it is classified as high or low. The OGTR will define the specific criteria for assessment and will reflect the effort required to process the application. This may include (but is not limited to) factors such as the level of risk, novelty, or technical difficulty associated with the activities intended to be carried out under the licence. The level of complexity will determine the application fee amount.

OGTR will also determine whether the activities proposed under the licence are research, pre-commercial or commercial.

Certification application fees will be structured in a similar manner. PC levels 1 & 2 (with the exception of large-scale PC 2 facilities) will be subject to a fixed fee. PC levels 3 & 4, and PC 2 large scale facilities will incur a higher fee. The increase in fee is attributed to the higher degree of effort and cost required from the OGTR for the assessment of these applications.

The imposition of fees lies at the OGTRs discretion, and they may choose to exclude some organisations from paying.

9.3. Stakeholder Engagement Plan - 2026/2027

The OGTR will maintain regular and ongoing engagement with stakeholders and sector leaders. A proactive approach to stakeholder engagement will enable the capture of valuable feedback, which can then be carefully considered in future fee reviews. This will ensure that the fee structure remains aligned with the evolving needs and expectations of the industry.

OGTR recognises that effective stakeholder engagement is critical to the successful design and implementation of cost recovery arrangements. As cost recovery is introduced through a phased approach, the OGTR will maintain ongoing engagement with regulated entities and other key stakeholders to ensure charging arrangements are transparent, practical and informed by stakeholder experience. Through these engagement mechanisms, the OGTR will continue to foster a collaborative relationship with stakeholders, provide clarity regarding proposed charging arrangements and implementation timeframes, and ensure stakeholder feedback is considered as part of ongoing review and refinement of the cost recovery model. This approach will support transparency, promote understanding of cost recovery arrangements and assist in ensuring the model remains practical, sustainable and aligned with the needs of the regulated sector. Engagement pathways include:

9.3.1. Governance Committee

To support the development and implementation of cost recovery arrangements, the OGTR has established a Governance Committee to provide oversight and assurance throughout the project. The Committee provides an important governance function by ensuring that cost recovery arrangements are developed consistently with the AGCF, Commonwealth Cost Recovery Guidelines and broader Government policy objectives.

The Committee meets bi-monthly to review project progress, monitor risks, consider key decisions and provide strategic guidance on the design and implementation of cost recovery arrangements. Decisions and action items are documented and tracked to support accountability, transparency and effective project delivery.

9.3.2. Industry Reference Group (IRG)

The OGTR has established the Cost Recovery Industry Reference Group (IRG) as a dedicated forum for consultation and discussion throughout the development and implementation of cost recovery arrangements. The Group provides an opportunity for stakeholders to engage directly with the OGTR and provide feedback on proposed cost recovery arrangements, consultation materials and implementation activities. The Group also assists the OGTR in identifying practical implementation

issues, risks and opportunities for improvement, while supporting clear communication between the regulator and regulated entities.

The Industry Reference Group is advisory in nature and does not participate in regulatory decision-making or Government decisions relating to cost recovery policy. Its purpose is to assist the OGTR in understanding the potential impacts of cost recovery arrangements across different parts of the gene technology sector and to provide practical insights that support effective implementation.

Membership of the Group is determined through an Expression of Interest process administered by the OGTR. The OGTR seeks balanced representation from organisations that may be affected by cost recovery arrangements, including licence and certification holders from a range of sectors and organisation types. Membership may include representatives from commercial biotechnology organisations, small and medium biotechnology companies, universities and research institutions, research organisations, clinical trial and contract research organisations, and State and Territory government agencies. The OGTR may periodically review membership to ensure the Group continues to provide broad and appropriate stakeholder representation.

The OGTR provides the Chair and secretariat functions for the Group and will facilitate regular meetings throughout the implementation of cost recovery. Feedback received through the Industry Reference Group will complement broader stakeholder consultation activities, including public consultation on the CRIS, targeted engagement activities and ongoing discussions with regulated entities.

9.3.3. Institutional Biosafety Committee (IBC) Forum

The OGTR has previously presented on the proposed cost recovery framework at the Institutional Biosafety Committee (IBC) Forum. The forum is attended by more than 150 participants representing a broad range of stakeholder groups, including research institutions, universities, state agencies, industry representatives and biosafety professionals.

Ongoing engagement with IBCs provides an important opportunity for stakeholders to gain an early understanding of the proposed model, ask questions, and provide feedback on the practical implications of cost recovery arrangements. Feedback received through this engagement activity will continue to inform the refinement and implementation of the cost recovery framework.

10. Consultation Process

Consultation on the proposed cost recovery arrangements and draft CRIS was undertaken between **[INSERT DATE]** and **[INSERT DATE]**.

Consultation activities included:

- publication of a draft CRIS and supporting consultation materials on the OGTR website (public consultation)
- meetings of the Industry Reference Group (IRG)
- engagement with industry peak bodies and representative organisations
- presentations and discussion sessions through the Institutional Biosafety Committee (IBC) Forum
- stakeholder information sessions and webinars
- written submissions from stakeholders
- targeted engagement with government agencies and other relevant regulatory bodies.

Consultation materials included information on:

- the proposed cost recovery model

- proposed fees and charging arrangements
- implementation timelines
- charging principles and policy rationale
- proposed exemptions and exclusions
- opportunities for future review and refinement.

10.1. Stakeholder Participation

10.1.1. Consultation Participation Summary

Engagement Activity	Participation
Consultation period	Date: from – to
Written submissions received	Number
IRG meetings conducted	Number
Peak body meetings conducted	
Webinar participants IBC Forum participants	
Consultation webpage views	
Organisations represented	

10.2. Key Consultation Themes – Infographic or written

- XXXX
- XXXXx
- XXXX

10.2.1. Summary of Stakeholder Feedback

Theme	Stakeholder feedback	OGTR response

10.3 Outcomes of Consultation

The OGTR appreciates the time and effort contributed by stakeholders throughout the consultation process.

Feedback received through consultation has assisted the OGTR to better understand the potential impacts of cost recovery arrangements across different parts of the gene technology sector and has informed the refinement of the charging model described in this CRIS.

As a result of consultation, the OGTR has:

- Outcome 1
- Outcome 2
- Outcome 3
- Outcome 4

The OGTR will continue to engage with stakeholders through the Industry Reference Group, peak body engagement and future consultation activities to ensure the cost recovery model remains transparent, practical and aligned with the needs of the regulated sector.

The feedback received through consultation was provided to the Assistant Minister for Health and Aged Care, the Hon Rebecca White MP for consideration alongside the proposed cost recovery arrangements and the final CRIS.

11. Communications Materials

The OGTR, in consultation through aforementioned stakeholder forums, will provide supporting materials for the implementation of cost recovery arrangements. These materials will be tailored and targeted appropriately.

Material will include:

- Explanatory and education materials, including potential case studies of how cost recovery would look in practice for various entities (administrative guide).
- FAQs
- Stakeholder and sector presentations.
- Key timeframes and timelines for cost recovery development and implementation published on OGTR website.
- Dedicated email inbox for enquiries.

12. Financial estimates

The proposed cost recovery fee schedule is designed to partially recover the OGTR's recoverable costs. The calculated recoverable expenses and fee revenue for the 2026-27 financial year have been adjusted for inflation using expertise-informed in-house forecasts of the Wage Price Index (WPI) for labour costs, and the Consumer Price Index (CPI) for non-labour costs. The estimates of expenses and revenue for the next five financial years is shown below (Table 13).

The expenses and revenue are modelled for five financial years as the Australian Government Cost Recovery Policy requires a periodic review of all existing and potential charging activities to be conducted at least once every five years.

Table 13: Financial estimates of the OGTR's expected recoverable expenses and fee revenue (under Phase 1, current legislation)

	2024-25	2025-26	2026-27	2027-28	2028-29
Expenses	\$2,707,701.26	\$1,193,252.72	\$1,229,934.05	\$1,267,260.11	Pending Phase 2 commencement
Revenue	\$1,467,701.26	\$1,511,189.24	\$1,555,861.12	\$1,601,383.06	Pending Phase 2 commencement

Balance	-\$1,240,000.00	\$317,936.53	\$325,927.06	\$334,122.95	Pending Phase 2 commencement
Cumulative balance	-\$1,240,000.00	-\$953,809.58	-\$651,854.12	-\$334,122.95	\$0.00
Explain material variance	The significantly greater expense compared with revenue in Year 1 pertains to the upfront cost associated with establishing a cost recovery scheme (specifically, upgrading the OGTR's client relationship management software and developing a payment gateway).				
Explain balance management strategy	The cost recovery scheme aspires to manage the ongoing balance through the design of its fees for applications, which it fully recovers on average as application costs are incurred. Some of the costs recovered through the annual fee are for costs incurred during the current financial year. The remaining costs recovered through the annual fee are capital expenditure outlays, which are fully recovered through fee revenue over five years.				

Source: Deloitte Access Economics.

13. Performance

13.1. Financial performance

The financial framework for the OGTR's governance is outlined in the Public Governance, Performance and Accountability Act 2013 (PGPA Act). To comply with the PGPA Act, the OGTR reports its financial performance to the Secretary, who serves as the Accountable Authority. The annual budgeted expenses versus actual expenses for the OGTR by the Department of Health, Disability and Ageing have been outlined below Table 14.

Table 14: OGTR annual budgeted expenses versus actual expenses 2020-2021

	Previous budget figures				Forward estimates			
	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26	2026-27	2027-28
Budgeted expenses	8.0	8.2	8.5	11.1	8.1	8.0	8.1	8.2
Estimated actual expenses	8.3	8.5	8.7	11.2	NA	NA	NA	NA

Source: Department of Health and Aged Care Portfolio Budget Statements

There is no existing data on revenue given the cost recovery scheme is being established for the first time. However, the performance of the cost recovery scheme will be closely monitored and evaluated in future reviews to ensure its effectiveness.

13.2. Non-financial performance

The primary objective of the OGTR is to protect human health and the environment through regulatory oversight of GMOs. To achieve this objective, the OGTR administers the Scheme, which involves assessing applications, granting approvals, and conducting monitoring and compliance activities for GMO approvals.

Performance targets are outlined in the Department of Health, Disability and Ageing Portfolio Budget Statements (PBS). PBS targets have been met as follows:

Performance Measure	2022-23	2023-24	2024-25

GMO licence decisions made within statutory timeframes	100%	100%	PBS target of $\geq 98\%$ achieved
Reported non-compliance with conditions of GMO approvals assessed	100%	99.1%	100%

14. CRIS approval and change register

Date of CRIS change

CRIS change

Approver

Basis of change

XX/XX/XXXX

DRAFT

Appendix A: Appropriateness of Charging for Regulatory Activities

Cost recovery involves Government entities charging individuals or non-government organisations some or all of the efficient costs of a specific Government activity. This may include goods, services, regulation, or a combination of these. The Australian Government Charging Policy (Charging Policy) sets out the framework under which Government entities design, implement and review cost-recovered activities.

The Charging Framework applies to non-corporate and corporate Commonwealth entities as defined in the *Public Governance, Performance and Accountability Act 2013*. The Department of Health, Disability and Ageing is a non-corporate Commonwealth entity.

The AGCF, including the Cost Recovery Policy, establish the principles that govern how Commonwealth entities design, implement and review cost recovery arrangements. The framework promotes transparency, accountability and consistency in regulatory charging and supports the efficient use of public resources.

The policy statement for government charging, as stated in the Australian Government's Charging Policy, is:

'Where specific demand for a government activity is created by identifiable individuals or groups, they should be charged for it unless the Government has decided to fund that activity. Where it is appropriate for the Australian Government to participate in an activity, it should fully utilise and maintain public resources, through appropriate charging. The application of charging should not, however, adversely impact disadvantaged Australians.'

Charging for licensing and certification provided by the OGTR is appropriate because:

- charging is an important means of improving the efficiency and equity with which Government services are provided;
- the charging of fees and a levy sends a price signal to individuals or groups about the cost or value of a Government activity;
- the services are requested by an identifiable group of parties who cause regulatory effort for the OGTR; and
- it supports the ongoing sustainability of the OGTR as a regulatory activity.

There are two types of cost recovery charges. The characteristics of a Government activity determine the type of cost recovery charge used:

Cost recovery fees will be charged where a direct relationship exists between the regulatory activity and the individual or organisation requesting that specific activity. All regulated entities are charged the same fee for the same activity. Under these circumstances, the activities performed, and their associated costs, are driven by a specific need and demand created by the applicant. For example, licence applications and certifications will be charged a cost recovery fee.

Cost recovery levy will be charged when the cost of the activity can be reasonably attributed to a broader group of organisations (or individuals) rather than a single entity. In these instances, the level of demand for Government activity or intervention is collectively driven by the industry rather than a single entity within it. For example, the associated costs of managing licences will be funded through a levy payable annually.

Appendix B: Cost associated with each step of licence and certification applications

Table 15: Average cost and proportion of total cost for each process step for DIR licence applications

Process step	Average cost (\$)	Proportion of total cost (percentage)
1. Completeness review and database entry	1,496	2.38
2. Suitability review	1,415	2.25
3. Public consultation	3,575	5.69
4. Risk assessment and draft licence conditions	31,785	50.55
5. Public notification and consultation (if required)	4,479	7.12
6. Final review and decision	18,843	29.97
7. Applicant and public notifications	1,287	2.05
Total	62,880	100

Source: Office of the Gene Technology Regulator.

Table 16: Average cost and proportion of total cost for each process step for DNIR licence applications

Process step	Average cost (\$)	Proportion of total cost (percentage)
1. Completeness review and database entry	1,136	5.96
2. Suitability review	578	3.03
3. Risk assessment and draft licence conditions	13,486	70.80
4. Public notification and consultation (if required)	1,467	7.7
5. Final review and decision	2,252	11.82
6. Applicant and public notifications	129	0.68
Total	19,048	100

Source: Office of the Gene Technology Regulator.

Table 17: Average cost and proportion of total cost for each process step for high-level containment certification applications

Process step	Average cost (\$)	Proportion of total cost (percentage)
1. Pre-application advice	102	1.90
2. Completeness review and database entry	44.2	0.82
3. Inspection	2,559	47.58
4. Post-inspection report and draft instrument	2,244	41.72
5. Review and decision	367	6.82
6. Applicant notification	62	1.15
Total	5,378	100

Source: Office of the Gene Technology Regulator.

Table 18: Average cost and proportion of total cost for each process step for low-level containment certification applications

Process step	Average cost (\$)	Proportion of total cost (percentage)
1. Completeness review and database entry	32	27.59
2. Assessment	50	43.10
3. Review and decision	16	13.79
4. Applicant notification	18	15.52
Total	116	100

Source: Office of the Gene Technology Regulator.