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

Questions and Answers

Cost Recovery

1. Why cost recovery is being introduced?

The National Gene Technology Scheme has been government funded for nearly 25 years. While cost recovery was intended from the outset, it was deferred to support the emerging biotechnology sector and encourage innovation. With advancements in the gene technology sector, the volume and complexity of regulatory activities undertaken by the OGTR has increased. 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.

2. What is a Cost Recovery Implementation Statement?

The Cost Recovery Implementation Statement (CRIS) is a public document that ensures transparency and accountability for the level of charges and demonstrates that the purpose for charging, as decided by government, is being achieved.

3. When will cost recovery commence?

Phase 1 of cost recovery arrangements are planned to commence on 1 March 2027.

4. What activities will be cost recovered?

The *Gene Technology Act 2000* and the *Gene Technology (Licence Charges) Act 2000* allow the OGTR to charge application fees for certifications and licences and annual charges for holders of licences.

5. What is the methodology used to calculate the cost?

The proposed costs have been developed using an Activity-Based Costing (ABC) methodology that links fees and charges 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. Further information on methodology is found within the CRIS.

6. How can I comment on the draft CRIS?

The draft CRIS and supporting documents are available on the OGTR website, the consultation hub or via the contact information listed below. You are invited to submit your written comments (via the consultation hub or by email) on the draft CRIS. Comments must be received by the close of the consultation period on 13 November 2026.

7. What are the next steps in the process?

Following the consultation period, the CRIS will be finalised, taking into account submissions received. A de-identified summary of feedback received and consideration of those comments will be included in the final CRIS. The OGTR will then seeking Ministerial approval of proposed cost recovery arrangements.

8. What is high and low complexity application categories?

Complexity for a licence application depends on various factors such as the novelty of the activity, the requirement for varying levels of scientific evaluation and risk assessment, previous assessment history, as well as consultation requirements in line with the *Gene Technology Act 2000*.

The below table provides examples of Licence types for illustration purposes.

Licence Type	High Complexity Examples	Low Complexity Examples
DIR (commercial/general release)	Commercial release of GM banana, GM tomato, COVID-19 vaccines	Commercial release of GM canola, GM cotton
DIR (limited and controlled release)	Clinical trial with GM bacteria, limited and controlled release of GM sorghum	Limited and controlled release of GM cotton, clinical trial with GM adenovirus
DNIR	Full gene drive research, in vivo CAR T-cell therapy, manufacture of live vaccines	Clinical trial with GM AAV, manufacture of proteins and antigens

9. How do commercial, pre-commercial and research activities differ?

Commercial activities

- Activities undertaken for marketing, commercial production, manufacturing, supply or widespread distribution.
- Usually involve larger-scale deployment and broader exposure considerations.

Pre-commercial activities

- Activities undertaken before commercial release.
- Includes many clinical trial applications (including Phase 1 clinical trials) and agricultural field trials conducted at scale.
- Designed to generate data to support future commercial decisions.

Research activities

- Proof-of-concept, experimental or exploratory work undertaken primarily for research purposes.
- Typically, earlier-stage activities with a research objective rather than commercial deployment.

OGTR recognises that many limited and controlled release applications are likely to be pre-commercial. However, some early-stage experimental releases may be considered research activities. Further guidance material will be provided prior to implementation. If you are unsure how your application may be classified, please contact OGTR for further advice.

10. Is the Annual Charge due per licence or per organisation?

The Annual Charge is due for each licence that an organisation holds regardless of whether it is active or not.

11. What is the first Annual Charge?

The Annual Charge is $3710. As a transition to the ongoing licence charge, in the first year, the annual charge will recognise the 1 March 2027 commencement (approximate cost of $1240 per licence and reflective adjustments to be made in the final CRIS). Invoices are expected to be issued in July 2027, for payment by September 2027.

12. Will receipt of cost recovery funds be used to fund more/new staffing positions in OGTR?

No. The introduction of cost recovery is not intended to fund workforce growth. Cost recovery will support the sustainability and ongoing delivery of existing regulatory services and help maintain current capability, including to meet statutory timeframes. Consistent with the Australian Government Charging Policy Statement, 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.

13. Why does extending a certification require submitting a new application, while extending the duration of a licence can be managed through a variation?

These are two different authorisations and processes. A variation to extend the date of a certification requires similar effort to assess as a new certification and can therefore be charged accordingly. This match in effort and assessment does not apply to variation of licences.

Version Control

Date	Version	Author	Updates
7 October 2026	1	Cost recovery team	Questions 1-7
4 November 2026	2	Cost recovery team	Added Questions 8-13