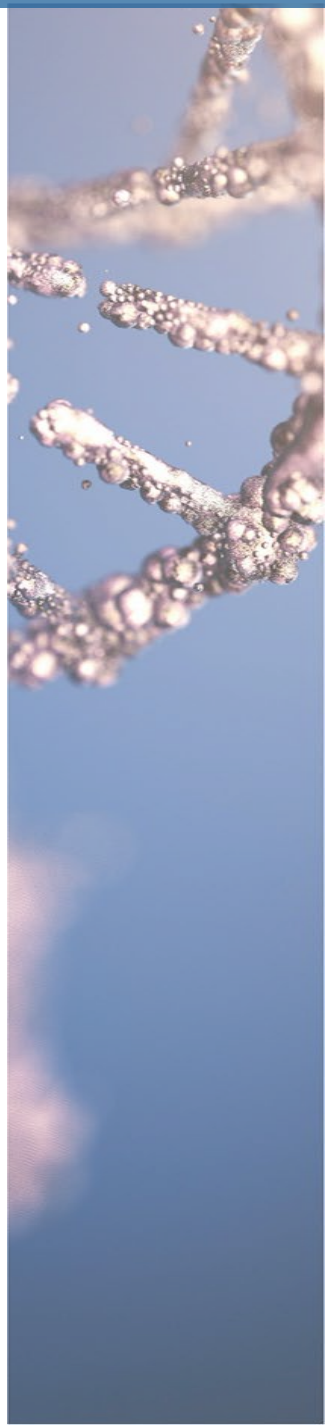
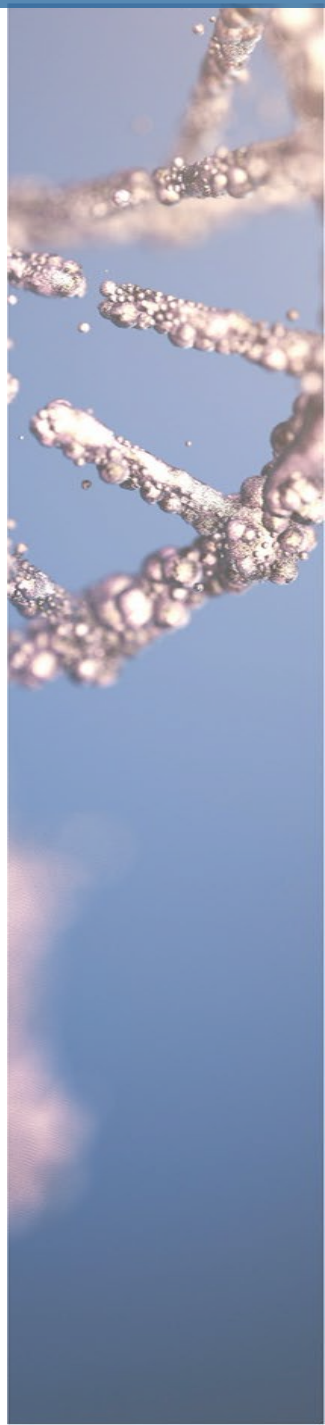
Cost Recovery Update



Why Cost Recovery?

- Mature regulatory scheme
- Government Budget decision
- Sustainable funding model
- User-pays principle under AGCF
- No change to regulatory independence



Cost Recovery Journey

2021

Recommendations for OGTR to commence cost recovery in a phased manner

DOH Portfolio Charging Review

2022

Economic Analysis

Deloitte's report on gene technology sector and sensitivities to cost recovery

2023

Use of Activities Based Costings to calculate actual costs and develop models

Development of Cost Recovery Models

2024

Consultation on Cost Recovery Models

Minister preference for waivers and exemptions for research explored with new models

2025

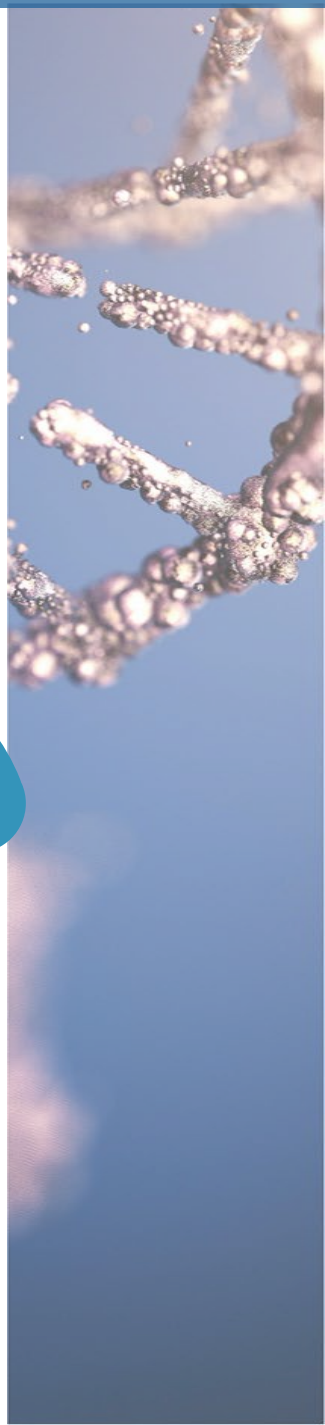
NPP included cost recovery options with base appropriation increase plus ASL

Efficiency Review and MYEFO Bid

2026

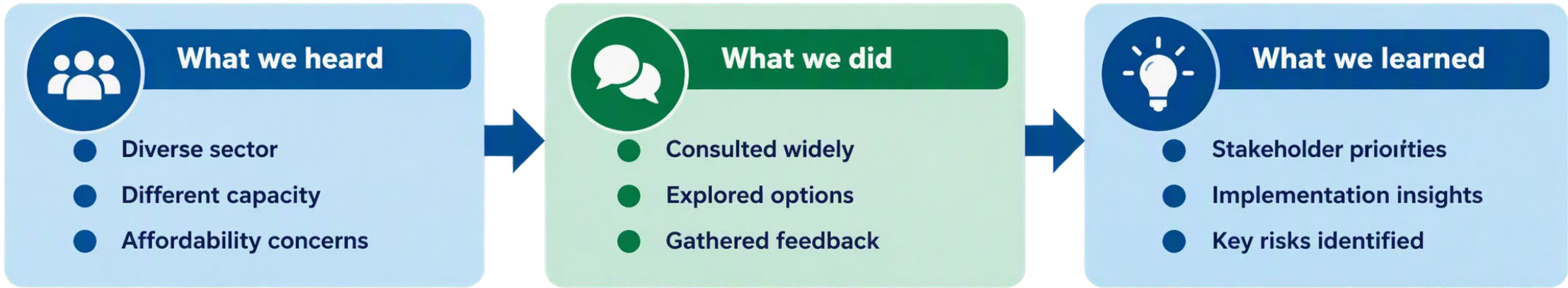
Budget 2026/27 NPP Bid

Government agreed to cost recovery in phase approach



Stakeholder Engagement

Listening, collaborating and informing better regulation



Engagement helps us make informed decisions and design effective, proportionate regulation

Budget Decision and Authority to Charge

Cost recovery will be implemented through:

- Phase 1 (1 March 2027) using existing legislative authority:



- Phase 2 (anticipated from 1 March 2029) through legislative amendments
  - ❖ application fees will be charged all application types
  - ❖ annual charges applying to other authorisation types

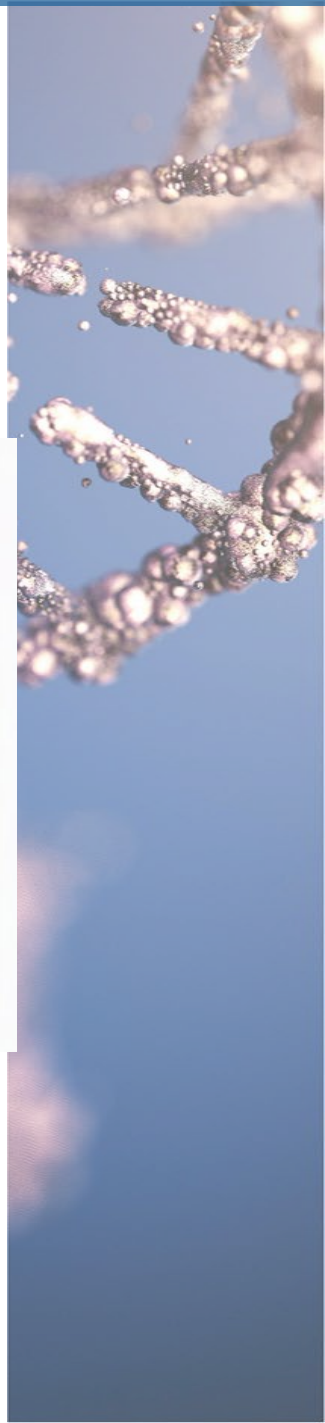
What you will not be charged for – Phase 1

Other regulatory activities

- Accreditation
- Secondary applications
- GMO Register
- NLRDs
- Confidential commercial information

Other responsibilities continuing to be funded by government

- General information advice
- Compliance activities
- Harmonisation of risk assessments
- Monitoring international practices



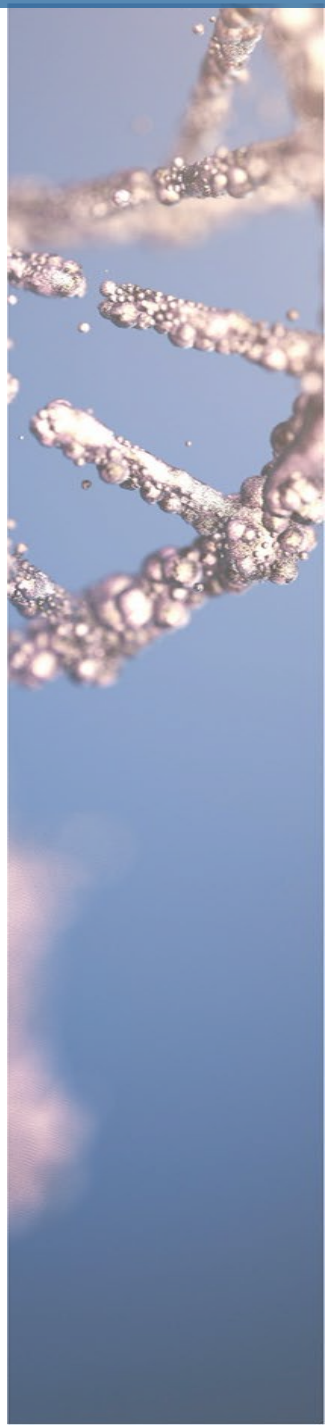
Budget Decision – Phase 1

for licence applications:

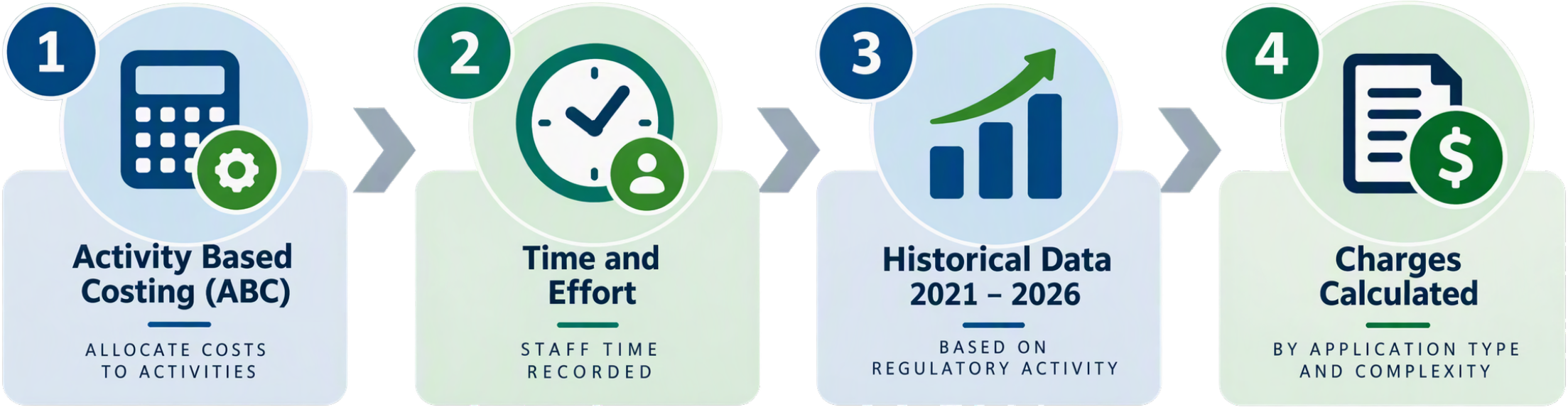
- Commercial applications will be charged at 50 per cent of actual costs
- Pre-commercial applications will be charged at 25 per cent of actual costs
- Research applications will be exempt from licence application fees.
- Annual charge will be imposed on all licence holders.

for certification applications:

- applications will be charged at 100 per cent of actual costs

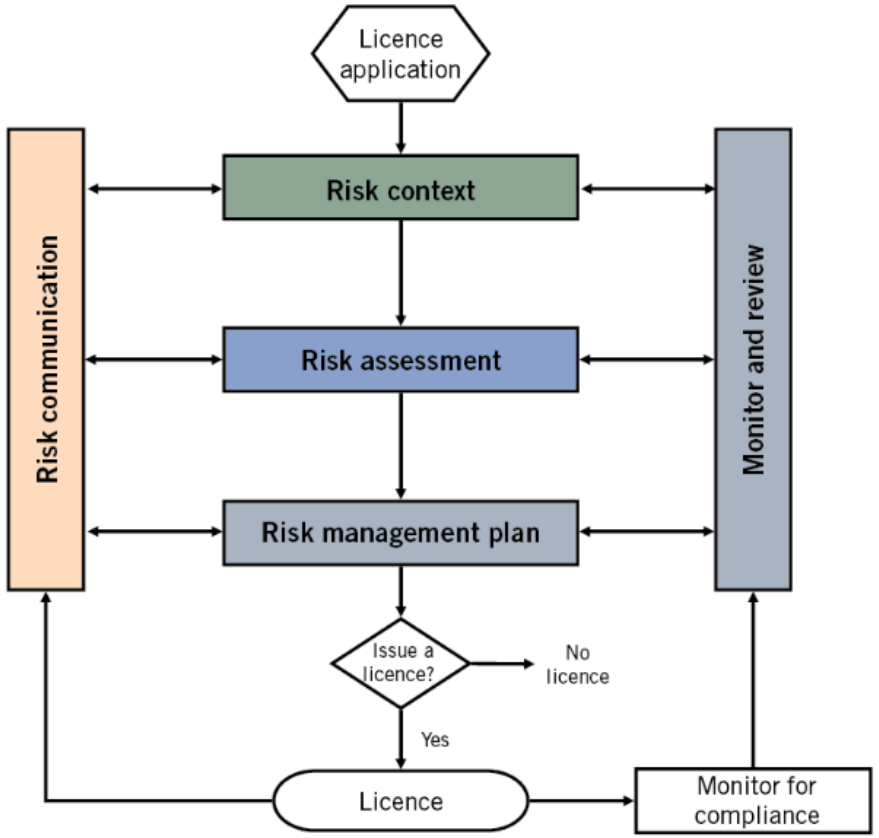


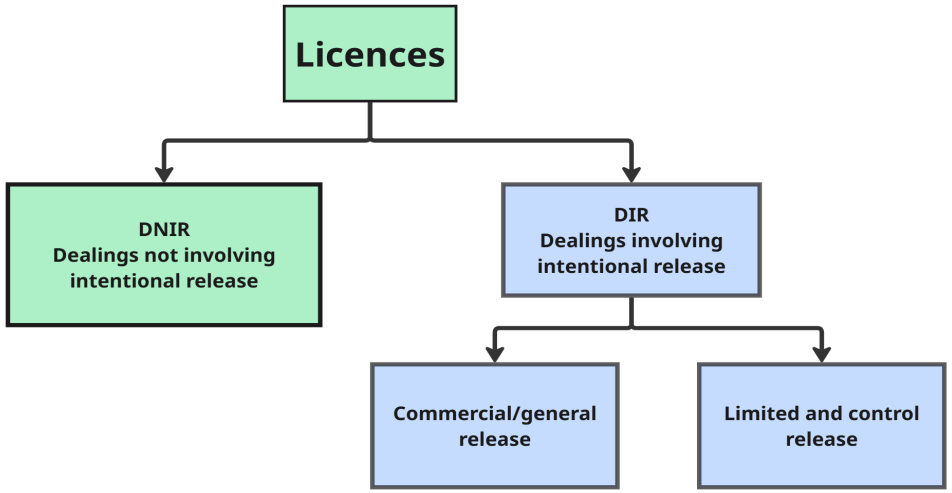
Cost Recovery Methodology

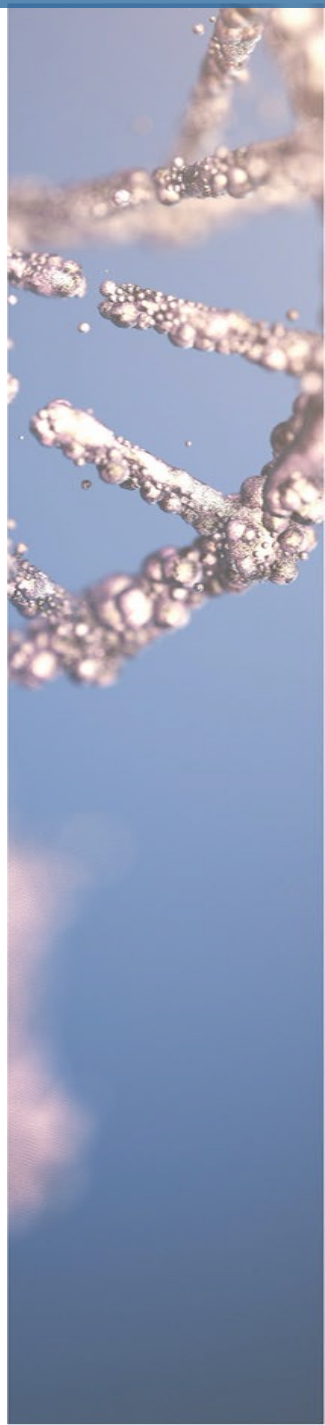


Licences

Licence required for GMO dealings that are not exempt or NLRDs

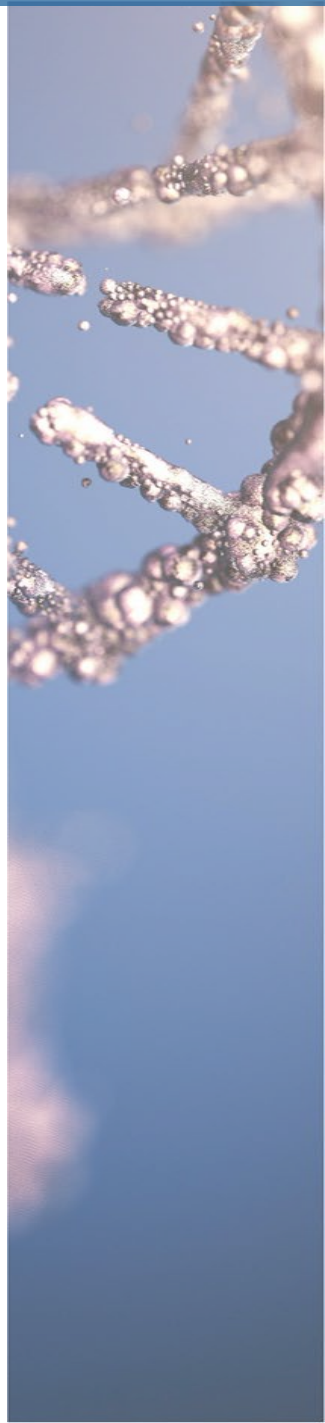






Licences

Licence	Activity type	Complexity	Examples	Consultation
DIR	**Commercial/ general**	**High**	Commercial release of GM banana, GM tomato, COVID-19 vaccines	2
		Low	Commercial release GM canola, GM cotton	
	L&C release • **pre-commercial** • **research**	**High**	Clinical trial with GM bacteria, L&C release of GM sorghum	1
		Low	L&C release of GM cotton, Clinical trial with GM adenovirus	
DNIR	• **Commercial/general** • **Pre-commercial** • **Research**	**High**	Full gene drive research, *in vivo* CAR T cell therapy, manufacture of live vaccines	If required
		Low	Clinical trial with GM AAV, manufacture of proteins and antigens	



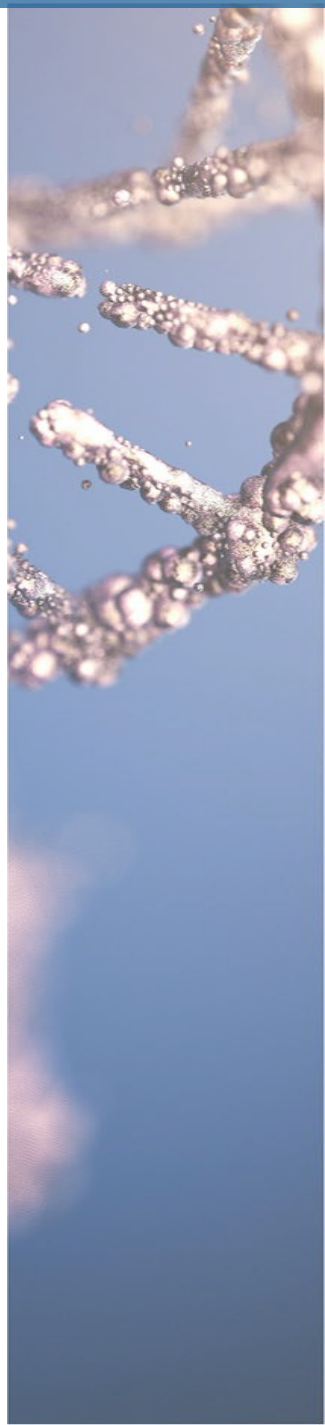
DIR Licence

Number of applications – 26 DIR licences (November 2021 to June 2026)



Proposed Licence Application Fees

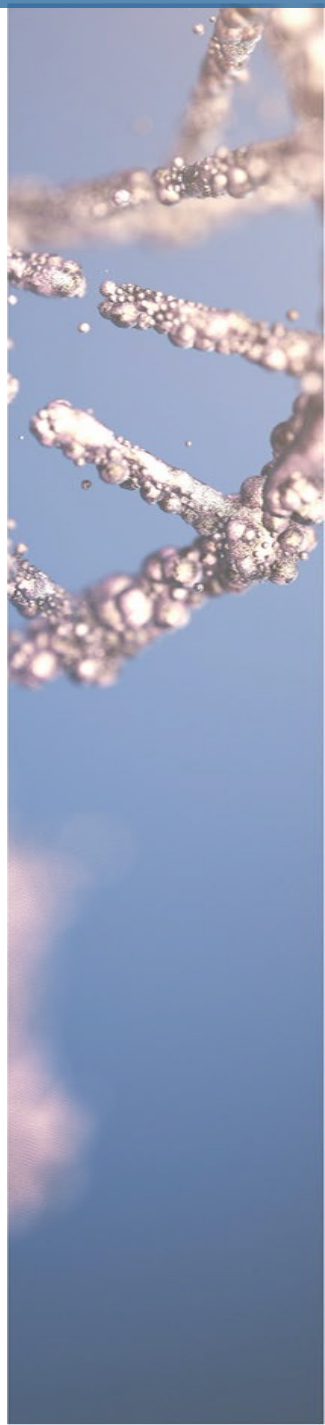
Licence Category	Complexity	Cost $	Activity type	Phase 1 approved rate	Phase 1 cost $ March 2027
DIR	High	$88,140	Commercial	50%	$44,070
			Pre-commercial	25%	$22,030
			Research	Exempt	$0
	Low	$56, 920	Commercial	50%	$28,460
			Pre-commercial	25%	$14,230
			Research	Exempt	$0
DNIR	High	$44,150	Commercial	50%	$22,080
			Pre-commercial	25%	$11,040
			Research	Exempt	$0
	Low	$17,260	Commercial	50%	$8,630
			Pre-commercial	25%	$4,320
			Research	Exempt	$0



Certification

- Certified against relevant Guidelines for the certification of physical containment facilities

Categories	Facility type	Notes
High level	PC2 Large Scale Facility PC3 Facility PC4 Facility	Involves inspection by OGTR staff Review of documentation
Low level	PC1 Facility PC2 Facility	Review of application form and floor plan



Certification



- Number of applications –
  - ❖ High Level – 44 (July 2022 to June 2026)
  - ❖ Low Level – 68 (Aug 2022 to Sept 2024)

Category	Containment	Cost $
Certifications	High level	$5,420
	Low level	$160

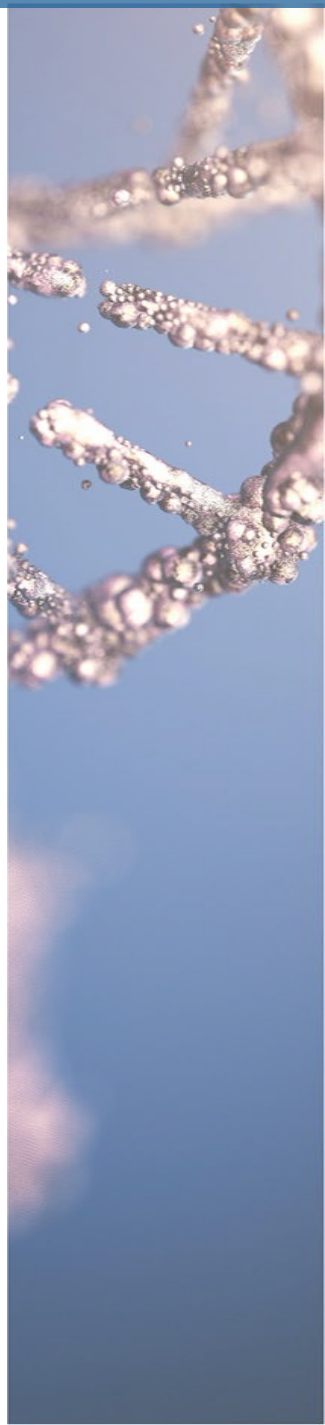
Annual Charge

- Recovers a portion of the ongoing regulatory activities required to administer and maintain the licence.

- Cost is $3710

Ongoing regulatory activities

- ❖ Post licence monitoring and auditing
- ❖ Stakeholder support & enquiries
- ❖ Regulatory guidance maintenance
- ❖ Database and information management
- ❖ Committee and secretariat functions
- ❖ Other regulatory activities



Performance

Timely assessments

Applications are processed within established regulatory timeframes.

Risk-based regulation

Assessment effort is proportionate to application complexity, with additional scientific. evaluation where required.

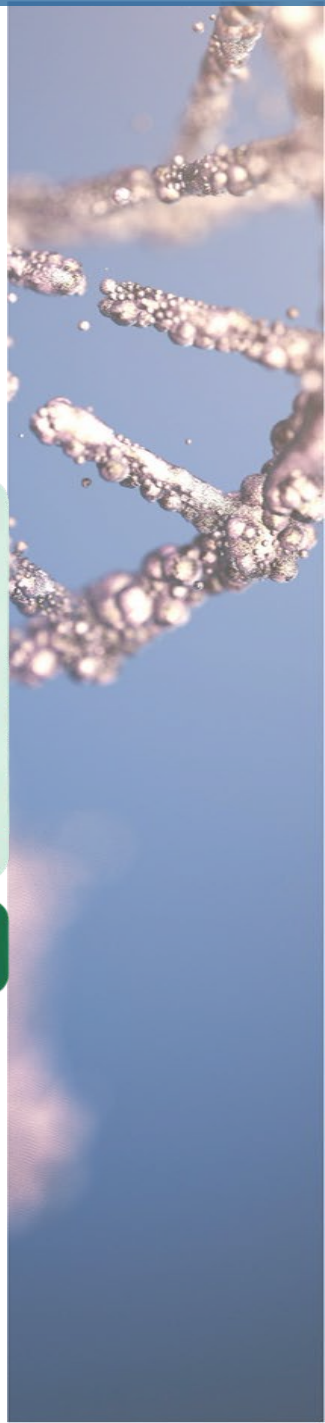
Consistent performance

Five years of application data demonstrates a stable and predictable regulatory process.

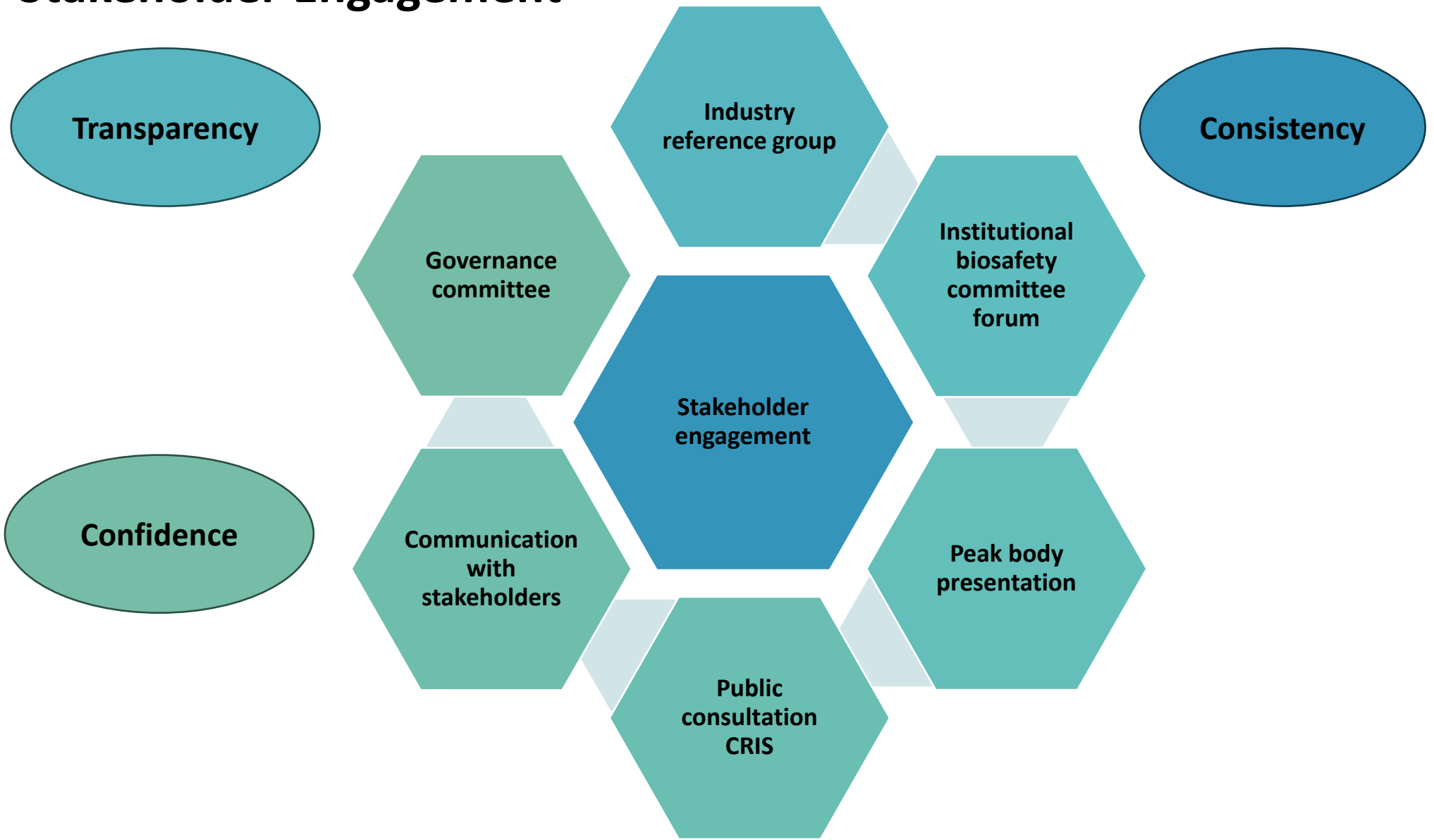
Supporting innovation

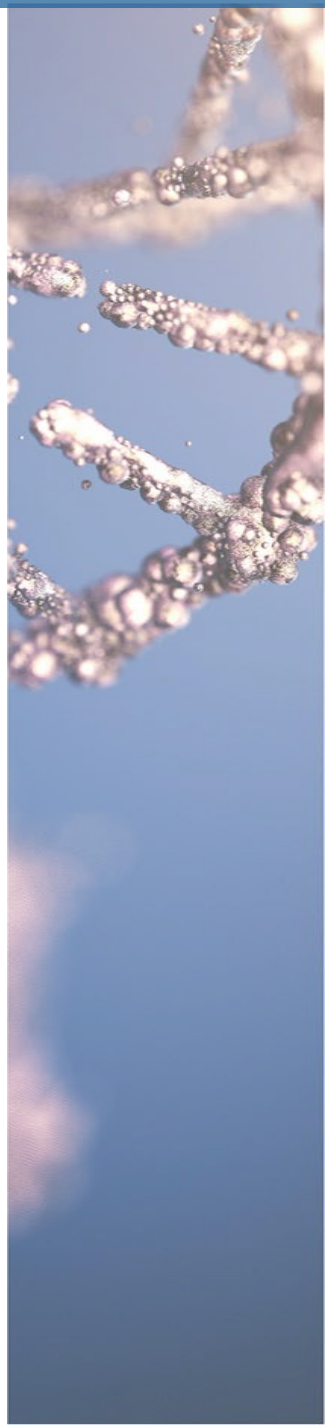
Timely, proportionate and evidence-based decisions enable safe innovation in Australia.

Supporting innovation through timely, proportionate and evidence-based regulatory decision-making.



Stakeholder Engagement





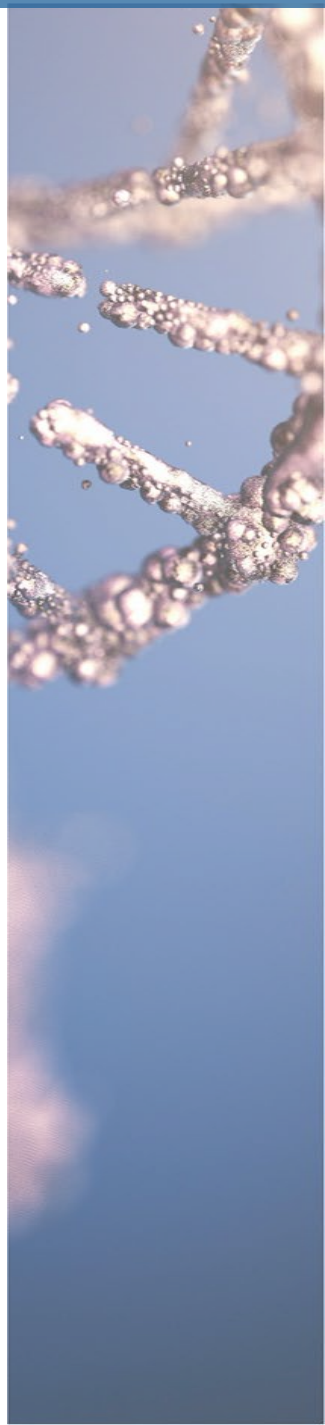
Feedback on Draft CRIS

Record

Consider feedback

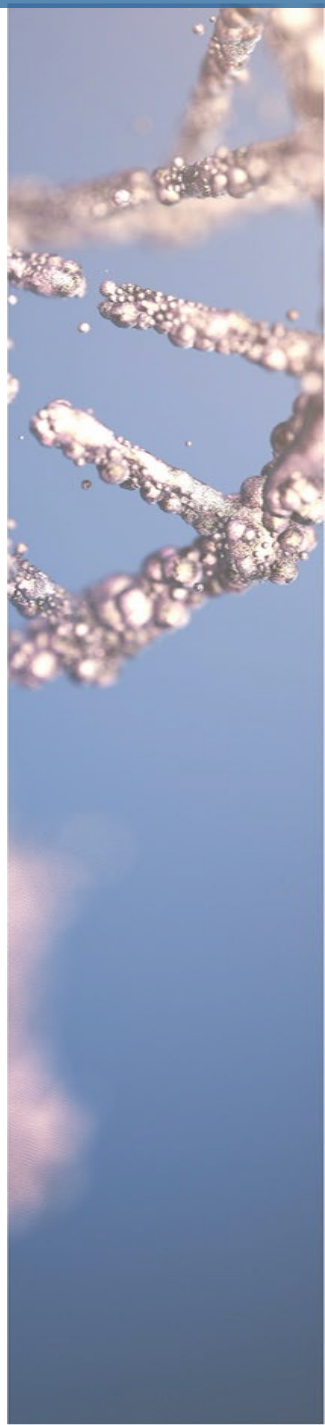
Action feedback

Publish in final CRIS



Key Milestones

Date	Milestone
7 October – 13 November 2026	Draft CRIS published and disseminated for public consultation.
15 October 2026	Cost recovery session at National Institutional Biosafety Committee (IBC) Forum.
Late October 2026	Inaugural Cost Recovery Industry Reference Group meeting. Initial meeting will be focused on CRIS and related feedback.
Late October 2026	Information webinar during draft CRIS consultation to address stakeholder questions and concerns.
December 2026/January 2027	Information webinar outlining how stakeholder feedback on the draft CRIS has informed the final CRIS. Progression of final CRIS and related Phase 1 cost recovery arrangements for Ministerial endorsement
February 2027	Related legislative instruments considered at Executive Council Meeting.
1 March 2027	Phase 1 Cost Recovery arrangements commence.



Australian Government
Department of Health, Disability and Ageing
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