Australian Government
Department of Health
Office of the Gene Technology Regulator

Celebrating 20 Years of OGTR 2001 - 2021

Retrospective report 4

Regulatory adjustments made in response to 20 years of innovation in gene technology

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Regulatory adjustments made in response to 20 years of innovation in gene technology

Australia's National Gene Technology Scheme

The Act and the Regulations, together with corresponding state and territory legislation, provide the legislative foundation for Australia's National Gene Technology Scheme (the Scheme). The Scheme protects the health and safety of people, and the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks by regulating certain dealings with GMOs.

Legislation for the nationally consistent Gene Technology Scheme was developed in consultation with all Australian jurisdictions and the Scheme is supported by the Intergovernmental Gene Technology Agreement 2001 (the Agreement) between the Australian Government and each state and territory. Under the Agreement, the states and territories have committed to maintaining corresponding legislation with the Commonwealth. The Scheme is overseen by the Gene Technology Ministers' Meeting (GTMM), a body made up of ministers from each jurisdiction, in accordance with the Agreement.

How does the Gene Technology Scheme keep up with scientific advances?

Ongoing advances in gene technology present exciting possibilities for innovation and growth. Gene technology legislation needs to flexibly respond to technological advances, while also providing legal certainty.

The Gene technology legislation is regularly reviewed and amended to ensure ongoing effective regulation of dealings with GMOs. There are two types of reviews, policy reviews of the Scheme (policy reviews) and Regulator initiated technical reviews of the Regulations (technical reviews).

Policy reviews

Policy reviews of the Scheme are required every 5 years, under the Agreement. Policy reviews are either commissioned or conducted by the GTMM (formerly known as the Legislative and Governance Forum on Gene Technology (LGFGT) from 2011 and the Gene Technology Ministerial Council (GTMC) from 2001). These comprehensive reviews examine the Scheme's operation as a whole and investigate whether it is achieving policy objectives. If needed, policy reviews can lead to broad changes to the gene technology legislation to improve operation of the Scheme. Changes can involve amendments to both the Act and the Regulations. Policy reviews guide the Scheme's ongoing strategic direction.

Technical reviews

Technical reviews can be initiated by the Regulator at any point in time. Technical reviews focus solely on technical aspects and are limited to issues that do not affect policy settings of the Scheme. These reviews tend to draw on operational experience to consider ways to enhance implementation of the Scheme. Technical reviews aim to;

- streamline administrative processes
- amend the Regulations to keep them up to date with new scientific advances
- ensure the level of regulation is commensurate with current understanding of risks posed by different GMOs; and
- improve legal clarity.

The Gene Technology Regulator recommends legislative amendments to the GTMM based on the outcomes of technical reviews.

Consultation is an important aspect of all Scheme reviews

Both Regulator initiated technical reviews and policy reviews of the Scheme involve substantial consultation with stakeholders and the public. Both types of review aim to meet the needs of research communities and industry in addition to addressing society's interests and concerns.

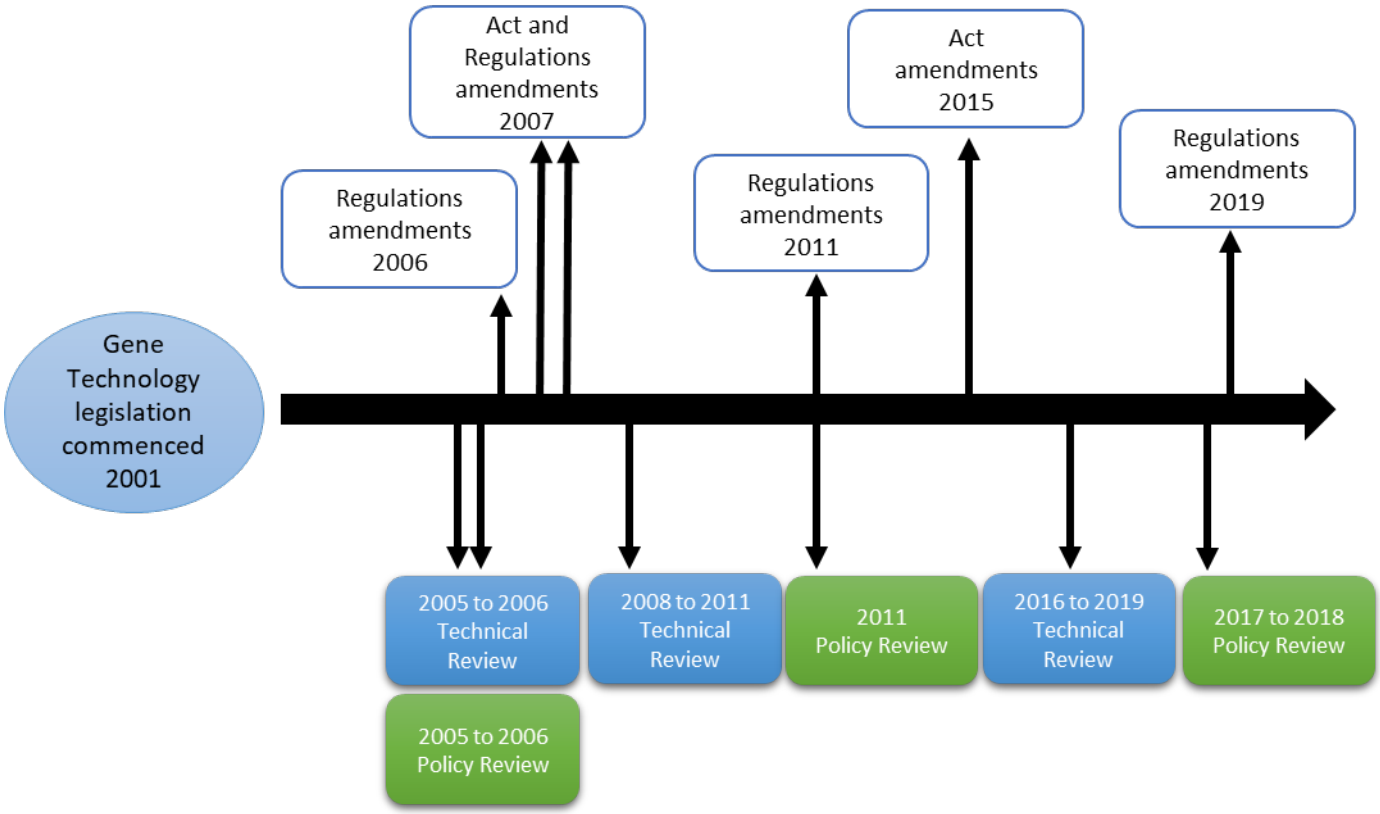
The table below summarizes important aspects of the different types of gene technology Scheme reviews.

Gene Technology Scheme Reviews	
Policy review	**Technical review**
•commisioned or conducted by GTMM/LGFGT •must be conducted every 5 years •review encompasses all aspects of the Scheme •involves consultation with stakeholders and public	•Regulator initiated •can occurr at any time •limited to reviewing technical aspects of the Scheme •involves consultation with stakeholders and public

Twenty years of Scheme reviews and regulatory changes for gene technology

Since the Scheme began in 2001, three policy reviews of the Scheme and three technical reviews were conducted. The first independent review and the first technical review occurred concurrently, while later reviews were conducted at different points in time. Every review of the Scheme over the last twenty years has resulted in recommendations for legislative change to continually improve the operation of the regulatory system.

The diagram below depicts reviews of the Scheme and resulting changes to the legislation since the commencement of the Scheme in 2001.



2005 to 2007 - First technical review and first policy review ran concurrently

Dr Sue Meek, the first Regulator, initiated a technical review that ran in tandem with the first policy review of the Act. The technical review used the operational experience of the first 4 years of the Scheme to investigate ways to streamline administrative processes and to improve clarity of the Regulations.

Additionally, the Regulator also revised the Certification Guidelines for contained facilities to achieve 'enhanced clarity and consistency' for regulated entities (DoHA 2007:3). Stakeholders were engaged and consulted during development of the revised guidelines and technical advice for applicants. This was in line with the high levels of transparency the Act requires in conducting assessments. Interested individuals and organisations were invited to comment and play a part in the review (DoHA 2007:40).

The Gene Technology Amendment Regulations 2006 implemented the changes proposed by the first technical review. Substantive changes to the Regulations included;

- addition of new definitions to clarify interpretation of the Regulations (e.g. advantage, characterised, code for, infectious agent, pathogenic determinant)
- removal of detailed information requirements for licence applications
- updating requirements for conducting NLRDs
- addition of Schedule 1A, which specifies techniques that are not gene technology
- clarification of and changes to;
  - exempt dealings
  - host/vector systems for exempt dealings
  - NLRDs, and

- licensable dealings.

The Gene Technology Ministerial Council (GTMC), now the GTMM, appointed an independent panel to conduct the first policy review in 2005, with Susan Timbs as its chair.

The first policy review of the Scheme was a statutory requirement under section 194 of the Act. The Act specified that a review be undertaken and tabled in Parliament by 21 June 2006, the fifth anniversary of the Act coming into force.

Extensive national public and stakeholder consultation ensured that the independent panel heard diverse community views. Almost 300 submissions were made in response to the terms of reference. These became five issues papers, based on the key ideas and concerns raised by individuals and organisations.

The independent review panel considered the submissions, issues raised during consultations, as well as the outcomes of the Regulator's technical review. Additionally, emerging trends and international developments in gene technology were taken into account. The statutory policy review report was released in April 2006.

The review found that the Act was protecting the health and safety of Australia's people and the environment. It noted the high level of transparency of the regulatory system, and that the regulatory framework was appropriate and being applied effectively. The policy review also compared the Australian Gene Technology Scheme to GMO regulatory frameworks in other countries. The Australian Scheme was regarded as one of the most rigorous, transparent and accessible regulatory systems.

The operational experience of the first 4 years of the Scheme uncovered the need for legislative changes to streamline the regulatory system. Significant changes to the legislation as a result of the outcomes of the policy review are summarised below.

Amendments to the Act

- introducing powers in the Act allowing the relevant minister to issue Emergency Dealing Determinations
- combining the two committees GTEC and GTCCC and their functions into one committee named GTECCC
- creation of two categories of Dealings involving Intentional Release (DIR) licences;
  - limited and controlled releases (e.g. for field trials) and
  - intentional releases of GMOs (e.g. for commercial release of GMOs)
- remove requirement for NHMRC to be consulted on all dealings involving intentional release
- ability for the Regulator to transfer certifications
- amendments to the Regulator's power to direct licence holders to comply
- introduction of licences relating to inadvertent dealings allowing disposal of GMOs
- addition of transport and disposal as dealings with GMOs in the definition of "deal with".

Amendments to the Regulations

- increased the statutory timeframe for assessing applications for intentional releases of GMOs and decreased the timeframe for assessing applications for limited and controlled releases
- introduced distinction between limited and controlled licence applications where the Regulator is satisfied that the proposed dealings do not pose significant risks, and applications where the Regulator is satisfied that at least one of the dealings may pose significant risks. Limited and controlled licence that may pose significant risks have an increased statutory timeframe for assessment.
- introduced a statutory timeframe for consideration of licence variations.
- changes in reporting requirements for notifiable low risk dealings

- changes to clarify classification of dealings with GMOs.

The *Gene Technology Amendment Act 2007* and the Gene Technology Amendment Regulations 2007 implemented the changes proposed by the independent policy review. These changes were agreed to in the state, territory and Australian governments' responses to the policy review recommendations.

2008 to 2011 - Second technical review

The Regulator, Dr Joe Smith, initiated the second technical review in response to suggestions from regulated organisations in 2008.

Dr Joe Smith said the review 'focused on ensuring classification and regulation of dealings with GMOs remain commensurate with risk and current scientific understanding' (DoHA 2011:4). Dr Smith added: 'In parallel with the Regulation review, the new Guidelines for Transport, Storage and Disposal of GMOs were finalised, consolidating and updating previous guidelines covering these activities' (DoHA 2011:4).

Following approval from the GTMC, the Gene Technology Amendment Regulations 2011 were made in June 2011. The technical changes related primarily to the conduct of contained GMO work, helping users better understand and comply with their legislative obligations. For example, the amendments clarified the requirements and responsibilities associated with undertaking laboratory-based research. Substantive changes to the Regulations included;

- updated requirements for oversight and timeframes for undertaking notifiable low risk dealings
- changes to classifications of GMO dealings to ensure that regulation remains commensurate with risk. Selected changes include;
  - reduction in regulation of certain human somatic cell therapies (e.g. CAR T cell therapies) from licensable dealings to exempt dealings, in line with increases in scientific knowledge
  - changes to classification of GMO dealings involving viral vectors
- formalisation of PC3 notifiable low risk dealings.

2011 to 2015 - Second policy review

Allen Consulting Group were commissioned by the Gene Technology Ministerial Council to undertake the second policy review of the Scheme in 2011. The review examined the efficiency and effectiveness of the Scheme as well as the interface between the Gene Technology Scheme and other regulatory bodies.

It drew on 48 submissions received from industry, government agencies, researchers, non-government organisations and individuals. The review team consulted with related regulatory agencies and the chairs of the two advisory committees that operate under the Act (GTTAC and GTECCC).

As before, the review found that the OGTR was operating in an effective and efficient manner to provide a rigorous, transparent regulatory system.

The 2011 review made 16 recommendations to improve the effectiveness and efficiency of the OGTR. Some were administrative or directed at states and territories.

The *Gene Technology Amendment Act 2015* implemented 5 of the 16 recommendations, as agreed by all governments in 2013. The changes aimed to reduce regulatory burden for the regulated community, and to aid better understanding of and compliance with their legislative obligations.

Building on the Regulator's practical experiences, minor amendments were made to improve the efficiency of the Scheme. Changes to the Act included;

- discontinuing requirement for the Regulator to provide quarterly reports to the Commonwealth Minister, for tabling in Parliament

- allowing the Regulator to authorise other appropriate dealings related to inadvertent dealings in addition to disposal (e.g. conducting experiments, transport)
- increasing flexibility of advertising requirements relating to DIR applications for public consultation purposes
- removing requirement for GM products authorised by other agencies to be included on the GMO Record
- providing greater flexibility for licence variation requirements.

2016 to 2019 - The third technical review

The Regulator initiated the third technical review in 2016 to clarify the regulatory status of organisms that were developed using a range of new technologies and ensure that the new technologies are regulated in a manner commensurate with the risks they pose.

Amendments to the Regulations proposed by the Regulator as a result of the review were considered by the LGFGT. The Regulator provided a Decision Regulation Impact Statement to support the LGFGT's consideration of the proposed amendments.

After more than 3 years of collaborative dialogue and extensive consultation, the LGFGT approved the amendments to the Gene Technology Regulations 2001, and the amendments were made on 4 April 2019.

The first phase of the Gene Technology Amendment (2019 Measures No. 1) Regulations 2019 came into effect on 8 October 2019. On 1 July 2020, the second stage saw minor administrative changes made to NLRD assessment and reporting requirements. On 8 October 2020, an item on the list of organisms that are not GMOs (Schedule 1 item 1) was repealed.

The amendments adjusted the level of regulation to match current understanding of the risks posed by different GMOs, to protect people and the environment. The amendments also resolved previous legal uncertainty about the regulation of gene editing techniques and resulting organisms. Legal clarity enables researchers and industry to progress their work more easily, increasing innovation and international competitiveness.

One gene editing technique, known as SDN-1, was excluded because the risks posed by SDN-1 organisms are no different to the risks posed by organisms carrying naturally occurring genetic variations. These GMOs cannot be distinguished from conventionally bred animals or plants.

Significant changes to the Regulations included;

- increased regulation of dealings involving gene drive organisms by making them licensable
- increased legal clarity for classification of GMOs. This includes clarifying classification of the following;
  - organisms created using gene editing technologies
  - organisms that are not GMOs
  - techniques involving introduction of RNA into organisms (e.g. RNAi)
  - host/vector systems and non-vector systems
- changes to requirements for NLRDs and reporting.

From 2017 - The third policy review

The LGFGT's in-depth third policy review of the Scheme began in July 2017 and was conducted by a collaboration of Australian, state and territory officials. They represented all Australian governments, independently of the Regulator. Once again, the review team consulted widely to assess whether the Scheme remained effective and fit for purpose into the future.

In keeping with the fast-changing pace of emerging technology, the review considered issues that relate to policy settings as well as technical aspects of the scheme. OGTR staff provided technical and operational information upon request, throughout the review process.

The final report of the third review was published in October 2018. As the Scheme still benefits both the public and industry at a broad level, there was no call to alter the object of the Act. The review also found that the Agreement was working well to support a national collaborative arrangement between jurisdictions and across relevant portfolios.

Forum ministers also recommended maintaining existing elements of the scheme that remain fit for purpose. These include the current governance mechanisms, the process trigger approach and the role of the Regulator.

The third policy review focussed on exploring ways to future-proof the Scheme, reduce unnecessary regulatory burden and remove regulatory duplication at the interface between OGTR and other regulatory bodies. The review recommended introducing additional risk-tiering into the Scheme and addition of principles-based regulation to certain aspects of the Scheme to facilitate flexibility while ensuring the level of regulation remains proportionate to risk.

The LGFGT endorsed all 27 recommendations in the review report and agreed to a forward work program, the review Action Plan. It prioritises activities to be undertaken to update the Scheme over the 2018–23 period.

The Department of Health Gene Technology Policy team are implementing the recommendations of the review, which is a substantial ongoing program of work. Implementation of the recommendations of the Third Review of the Scheme will enable continuing improvement and adaptability of the National Gene Technology Scheme.

Future regulatory changes to the National Gene Technology Scheme

Policy reviews and technical reviews of the Scheme are essential to maintain the efficiency and effectiveness of the National Gene Technology Scheme going into the next twenty years and into the future to maintain the objectives of the Act to protect human health and the environment.

Forward-looking legislation allows the Scheme to support innovation into the future. Access to innovative products is essential for economic competitiveness and may contribute to environmental protection.

2001	• Commencement of Gene Technology legislation
2005 to 2006	• First Technical Review
2005 to 2006	• First Policy review
2006	• Regulations amendments 2006
2007	• Act amendments 2007
2007	• Regulations amendments 2007
2008 to 2011	• Second Technical Review
2011	• Regulations amendments 2011
2011	• Second Policy Review
2015	• Act amendments 2015
2016 to 2019	• Third Technical Review
2017 to 2018	• Third Policy Review
2019	• Regulations amendments 2019

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Shortened forms

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