Australian Government

Department of Health and Aged Care
Office of the Gene Technology Regulator

Consultation on proposed minor and technical amendments to the Gene Technology Regulations 2001

November 2024

1. Introduction

Australia is committed to the World Health Organization's Global Polio Eradication Initiative[1]. Australia was verified as polio-free in 2000, and the Australian Interim Centre for Disease Control has a program of work to maintain this polio-free status[2].

To support this program and fulfill Australia's international obligations, Australia's designated Poliovirus Essential Facility must be certified for compliance with the Global Action Plan for Poliovirus Containment by May 2025. An audit of the facility is an essential step towards certification, and ongoing audits are needed to maintain certification. Inspectors appointed under the *Gene Technology Act 2000* (the Act) have been identified as the most appropriately skilled and qualified to audit the Poliovirus Essential Facility. Amendments to the Gene Technology Regulations 2001 (the Regulations) are necessary to facilitate the inspectors taking up this new role.

The Gene Technology Regulator (the Regulator) proposes to also make minor and technical amendments to the Regulations at the same time. As noted in the Regulator's last Technical Review of the Regulations[3], amendments are periodically needed to make the legislation reflect current technology and scientific knowledge, and to provide clarity about the scope of regulation. The technical amendment proposals are the subject of this consultation.

Concurrently, the Department of Health and Aged Care (the Department) is continuing to progress legislative changes to complete implementation of the Third Review of the Scheme[4]. A draft Gene Technology Amendment Bill was the subject of a recent consultation[5], and the Department will be consulting separately in due course on amending regulations.

2. Background

2.1 Overview of the National Gene Technology Scheme

Australia's National Gene Technology Scheme (the Scheme) is comprised of the Commonwealth Act and Regulations, and corresponding State and Territory laws. The Scheme is overseen by the Gene Technology Ministers' Meeting[6], a body made up of ministers from each jurisdiction, in accordance with the Intergovernmental Gene Technology Agreement[7].

The object of the Act 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 those risks through regulating certain dealings with genetically modified organisms." The Scheme focuses on live and viable genetically modified organisms (GMOs) and managing any risks they pose as a result of gene technology. While the object of the

[1] https://polioeradication.org/

[2] https://www.health.gov.au/our-work/polio-surveillance-program

[3] https://www.ogtr.gov.au/about-ogtr/legislative-reviews#20162019-technical-review-of-the-gene-technology-regulations-2001

[4] https://www.genetechnology.gov.au/reviews-and-consultations/past/2017-third-review

[5] https://www.genetechnology.gov.au/reviews-and-consultations/current/proposed-amendments-gene-technology-act-2000

[6] https://www.genetechnology.gov.au/about-the-national-scheme/how-it-works/ministers-meeting

[7] https://www.genetechnology.gov.au/about-the-national-scheme/how-it-works/national-agreement

Scheme is to protect people and the environment, the framework to achieve this also provides a clear regulatory pathway from research to market for GMOs.

2.2 Maintaining the legislation

All dealings with GMOs must be conducted in accordance with the Act, the Regulations and, where applicable, corresponding State and Territory legislation. As such, it is necessary to ensure that each piece of legislation remains up to date and fit for purpose.

Amendments to the Regulations have occurred through three technical reviews (amendments commencing in 2007, 2011 and 2019), the 2005-6 statutory review of the Act and several other consequential amendments. Many of the previous amendments to the Regulations have related to technical and operational matters that have enhanced the effectiveness of the Scheme and assisted user compliance by making the Regulations clearer and easier to understand. The technical amendment proposals described in this paper are also for this purpose.

2.3 Purpose of this consultation

The Regulator is consulting to seek the views of anyone likely to be affected by the proposed amendments. Feedback is specifically sought on whether the proposed minor and technical amendments described below would sufficiently improve clarity in the legislation, and on the impact the proposed amendments would have on regulated stakeholders.

This consultation is not seeking to identify additional aspects of the Regulations to amend. The Department's process to implement broader reforms to the Scheme is the appropriate place for any proposals to be raised, where they can be considered in the context of the full suite of reforms under development. Also, because there is limited time before the proposed amendments to enable Poliovirus Essential Facility audits are required, the Regulator would have no opportunity to consult further on any new proposals to seek the views of other stakeholders.

2.4 Next steps

Submissions received through this consultation process will be taken into account by the Regulator in drafting and finalising the proposed amendments. A summary of submissions and general response to the issues raised will be published by the Office of the Gene Technology Regulator (OGTR).

The Regulator will provide advice to the Gene Technology Ministers' Meeting regarding the finalised amendment proposals, as required by clause 40 of the Intergovernmental Gene Technology Agreement. If there is agreement, the OGTR would commence the Commonwealth regulation-making process. Throughout this process OGTR would keep regulated stakeholders up to date with any developments that might affect them, and post updates on the OGTR website.

3. The amendment proposals

Described below are the technical amendments the Regulator is proposing to accompany the amendment necessary to support certification of Australia's Poliovirus Essential Facility. These proposals relate to:

- updated names of prescribed authorities for licence consultations
- operational matters for two expert advisory committees, the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Ethics and Community Consultative Committee (GTECCC)
- adjustments and clarifications to the lists of techniques that are not gene technology and organisms that are not GMOs.

3.1 Administrative proposals

3.1.1 Prescribed authorities for licence consultations

The Act requires that the Regulator, when assessing applications for GMO licences, must prepare a risk assessment and risk management plan. Regulation 9 prescribes the Commonwealth authorities and agencies that the Regulator must seek advice from in relation to the risk assessment and risk management plan.

An amendment to regulation 9 is proposed to reflect changes to chemicals regulation that occurred in 2020, when the National Industrial Chemicals Notification and Assessment Scheme was replaced by the Australian Industrial Chemicals Introduction Scheme[8].

3.1.2 Committees

The Act establishes two expert advisory committees, GTTAC and GTECCC. The Regulations prescribe some matters in relation to committee members, including resignation and disclosure of interests. Note that regulation 31 has the effect that regulations for GTTAC also apply to GTECCC.

The Regulations set out how a member or expert adviser may resign, but do not specify when a resignation has effect. An amendment to regulation 19 is proposed to clarify that resignation takes effect on the day the Minister receives the notice of resignation, if the notice does not specify a later day.

Regulation 20 requires members to disclose their interests in matters being considered at committee meetings and prohibits members who have made a disclosure from taking part in the committee's decision about that matter. Amendments are proposed to make the requirements for management of conflicts of interest more contemporary and better aligned with approaches to advisory committees in other legislation.

The proposed change is to enable the committee to determine that a member who has disclosed an interest may participate in committee consideration of the relevant matter. The committee may consider this is appropriate if, for example, the member's disclosure does not present an actual or potential conflict. This amendment would help ensure that the committees can draw on the most applicable member expertise when advising the Regulator, where that is appropriate in light of declared conflicts. The member would not be present while the committee considers making the determination, and minutes of the meeting would

[8] https://www.industrialchemicals.gov.au/about-us/who-we-are-and-what-we-do

record any determinations. If the committee does not make a determination in relation to a member's declaration of interests, that member will be automatically excluded from committee considerations and decision-making on that matter.

3.2 Techniques that are not gene technology and organisms that are not GMOs

Schedules 1A and 1 of the Regulations, respectively, prescribe techniques that are not gene technology and organisms that are not GMOs. Amendments to these schedules are required to ensure the scope of regulation is clear to regulated entities and the broader community in light of ongoing technological changes.

3.2.1 Transfer of chloroplasts, mitochondria, and nuclei

Mitochondria and plastids (e.g. chloroplasts) are organelles within plant and animal cells that have their own genomes, separate to the much larger genome in the cell nucleus. Transferring chloroplasts or mitochondria from the cells of one organism to the cells of another organism is a technique used in plant and animal research. The Act and Regulations do not specifically address whether transferring plastids or mitochondria is a gene technology technique, where the organelle being transferred has not been genetically modified.

Somatic cell nuclear transfer, also known as cloning, is currently listed as a technique that is not gene technology, provided that it does not involve genetically modified material. Nuclear transfer techniques other than somatic cell nuclear transfer have developed and come into more widespread use, particularly in research. The legislation does not address these techniques.

Techniques to transfer unmodified nuclei, mitochondria and plastids have similar outcomes to several techniques that are not gene technology, including conventional breeding, somatic cell nuclear transfer, and cell and protoplast fusion. An amendment is proposed to list these transfer techniques as techniques that are not gene technology by expanding item 1 of Schedule 1A. This would only relate to techniques that do not involve any genetically modified material. This amendment would resolve questions as to whether these techniques are or are not gene technology and provide treatment that is consistent with somatic cell nuclear transfer.

3.2.2 Introduction of nucleic acids

In recent years, techniques that involve applying nucleic acids to cells have developed and diversified. Amendments to item 11 of Schedule 1A are proposed to more clearly address the regulatory status of some of these techniques.

Antisense oligonucleotides (ASOs) are short, single-stranded oligonucleotides that target and bind to RNA in cells and modulate how much protein is expressed from a gene. Gene expression is reduced, just as gene expression can be reduced in response to environmental changes or as a result of natural genetic mutations. The effect of applying ASOs is also equivalent to the effect of RNA interference, a technique that is not gene technology (Schedule 1A, item 11), however the legislation does not currently address ASOs. An amendment is proposed to add application of ASOs to the list of techniques that are not gene technology.

It is also proposed to extend item 11 of Schedule 1A to technologies such as mRNA vaccines to provide clarity about the status of mRNA-based techniques. Introducing RNA that can be transcribed to a protein has an effect equivalent to introducing the expressed protein into an organism by other means. mRNAs have a time-limited effect because they degrade, and their

expressed proteins also degrade. An amendment is proposed to make the status of this technique clear to regulated entities, and equivalent to applying protein to an organism.

Schedule 1A, item 11 is proposed to be amended so that it provides that introduction of nucleic acid or nucleic acid analogues into an organism is not gene technology provided that it:

- cannot give rise to an infectious agent
- does not alter the organism's genome sequence, and
- if the introduced nucleic acid is DNA, it cannot be transcribed.

This proposed amendment would not change the status of RNAs that are themselves GMOs. Dealings with those GMOs would continue to be regulated.

3.2.3 Exchange of DNA

Item 6 of Schedule 1 describes organisms that are not GMOs that are the result of an exchange of DNA within a species. While the item wording does not refer to microorganisms, the explanatory statement to the principal regulations describes this item in comparison to naturally occurring genetic exchange in some microorganisms. Amendments are proposed to specify that item 6 relates only to microorganisms. This would make it clear that this item does not provide an exclusion for higher organisms with cisgenic and intragenic modifications.

3.2.4 Epigenetic modifications

Epigenetic modifications are chemical changes to the genome, including DNA methylation and histone acetylation, that do not modify the DNA sequence. Epigenetic modifications can result in changes to the level of expression of genes; this is similar to the effect of ASOs described above. Natural environmental stimuli can lead to epigenetic changes, as can gene technology techniques.

The gene technology legislation does not directly address the status of organisms with epigenetic modifications as a result of gene technology techniques. To provide clarity about their status, it is proposed these organisms be listed as organisms that are not GMOs provided that the organism has no other modifications that occurred because of gene technology. This would give these organisms the same status as organisms with naturally occurring epigenetic modifications.

3.3 Implementation approach

If the Gene Technology Ministers' Meeting approves the finalised amendment proposals, the Regulator prefers to implement the amendments at the earliest opportunity. This would mean that the proposed amendments to items of Schedules 1A and 1 of the Commonwealth Regulations would commence the day after amendment regulations are made and registered. Amendments to state and territory gene technology laws would follow.

Regulated stakeholders who might be impacted negatively by this implementation approach are encouraged to make a submission. This would enable the Regulator to consider the regulatory burden implications and whether a different implementation approach is necessary to smoothly transition from the current legislation.

4. Consultation questions

The Regulator seeks feedback on the amendment proposals. The consultation questions below aim to elicit information the Regulator requires to finalise the proposals:

1. What are your views on the proposed amendments? Please provide an explanation.

2. Would the proposed amendments to Schedules 1A and 1 clarify how the techniques and organisms described above are regulated under the Scheme? Please identify any aspects you think need better clarity.

3. Would any of the amendment proposals change the regulatory burden on you from the Scheme? Identify any matters you think might impact the implementation approach.

Submissions can be made through the Department of Health and Aged Care consultation hub. **Submissions close on Sunday 8 December 2024.**