EXPLANATORY STATEMENT

Gene Technology Act 2000

Gene Technology Amendment (Minor Measures) Regulations 2025

The *Gene Technology Amendment (Minor Measures) Regulations 2025* (the Regulations) amend the *Gene Technology Regulations 2001* (Principal Regulations) to give the Gene Technology Regulator (the Regulator) an additional function enabling appointed inspectors to audit Australian laboratories that hold poliovirus. Australia's designated Poliovirus-Essential Facility must be audited in order to meet Australia's international obligation that the facility be certified for compliance with the World Health Organization's Global Action Plan for Poliovirus Containment. The Regulations also clarify and update exclusions to the definitions of "gene technology" and "genetically modified organism", and update administrative matters related to statutory advisory committees and agencies the Regulator must consult on aspects of licence applications.

The *Gene Technology Act 2000* (the Act) establishes the Australian Government's component of the nationally consistent scheme for regulating dealings with genetically modified organisms (GMOs) to protect the health and safety of people and the environment. The Regulator is a statutory office holder responsible for performing functions and exercising powers under the Act.

The purpose of the Regulations is to enable inspectors appointed under the Act to audit laboratories that hold poliovirus, to clarify the legislation to assist users to better understand and comply with their legislative obligations, and to update administrative matters. Specifically, the Regulations amend the Principal Regulations to:

- confer a new function on the Regulator, of making inspectors available to undertake inspections and audits of laboratories in Australia that hold poliovirus;
- clarify and update items on the lists of techniques that are not taken to be gene technology for the purposes of the Act, and organisms that are not taken to be GMOs for the purposes of the Act;
- update the list of agencies and authorities the Regulator must consult in relation to licence applications, risk assessments and risk management plans;
- specify when any resignation by a statutory advisory committee member or an expert adviser takes effect; and
- modernise requirements for managing potential conflicts of interest declared by statutory advisory committee members.

Subsection 193(1) of the Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The Regulations commence on the day after registration on the Federal Register of Legislation.

Between 11 November 2024 and 8 December 2024, public consultation on the amendments described above was undertaken. The consultation was notified to subscribers to OGTR News, organisations accredited under the Act and institutional biosafety committees. Submissions were sought on whether the proposed amendments would improve clarity, how the amendments would change regulatory burden, and the general views of submitters on the proposals. During the 4 week consultation period a total of 15 submissions were received from the research sector (universities, research institutes and researchers), agriculture-related peak bodies, government agencies, one company and one non-government organisation. Submitters generally indicated they would benefit from improved clarity in the legislation. Submitters that are regulated under the Act indicated that their regulatory burden would be either unchanged or reduced as a result of the amendments, for example, through improved clarity of regulatory requirements. The amendment proposals received varying degrees of support from submitters and the issues raised by submitters did not warrant changes to the proposals. Submitter suggestions to improve clarity were taken into account in finalising the Regulations.

The Gene Technology Agreement 2001, made by the Commonwealth, the States, the Australian Capital Territory and the Northern Territory, requires that proposed amendments to legislation forming part of the national legislative scheme must be approved by a two-thirds majority of members. The Regulations have been approved in the manner required under the Gene Technology Agreement 2001.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the Regulations are set out in **Attachment A**.

This instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

Authority: Subsection 193(1) of the *Gene Technology Act 2000*

ATTACHMENT A

Details of the proposed *Gene Technology Amendment (Minor Measures) Regulations 2025*

Section 1 - Name of Regulations

This section provides that the title of the Regulations is the *Gene Technology Amendment (Minor Measures) Regulations 2025.*

Section 2 - Commencement

This section provides that the Regulations commence on the day after registration on the Federal Register of Legislation.

Section 3 - Authority

This section provides that the *Gene Technology Amendment (Minor Measures) Regulations 2025* is made under the *Gene Technology Act 2000*.

Section 4 - Schedules

This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Part 1—Main amendments

Item [1] – regulation 5A

This item amends Principal Regulation 5A to confer an additional function on the Regulator, to make inspectors available to undertake inspections and audits, in relation to the containment of poliovirus, of laboratories in Australia that hold poliovirus. An audit of Australia's designated Poliovirus-Essential Facility is an essential step towards the facility being certified for compliance with the World Health Organization's Global Action Plan for Poliovirus Containment. Ongoing audits will be needed to maintain certification.

Item [2] – regulation 9

This item amends paragraph 9(d) of the Principal Regulations to refer to the Australian Industrial Chemicals Introduction Scheme instead of the National Industrial Chemical Notification and Assessment Scheme. This reflects changes to industrial chemicals regulation that occurred in 2020.

Items [3]-[4] – regulation 19

These items amend Principal Regulation 19 to clarify when the resignation of an advisory committee member or expert adviser takes effect. A notice of resignation will only be able to have effect on or after the day the notice is received by the Minister.

Item [5] – regulation 20

This item amends Principal Regulation 20 to change requirements relating to the disclosure of interests by members of the Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative Committee, in relation to matters to be considered at a meeting of the committee. Disclosures by members must continue to be recorded in the minutes of meetings. Unless the committee has determined otherwise, a member who disclosed interests in a matter must not be present during committee deliberations on the matter or take part in committee decisions on the matter. The committee may make a determination that a member could do otherwise. For example, the committee could determine that a member who has disclosed a possible conflict of interest in relation to a matter the committee is about to consider can participate fully in deliberations and decisions on the matter on the basis that the committee does not consider the member to have a material conflict. The member must not be present during committee deliberations for the purpose of making a determination, and the determination must be recorded in the minutes of the committee meeting.

Items [6]-[7] – Techniques that are not gene technology

These items amend table items of Schedule 1A to the Principal Regulations (techniques that are not gene technology). Schedule 1A supports Principal Regulation 4, listing techniques that are not gene technology for the purposes of the definition of "gene technology" in the Act. This provides clarity about the status of the described techniques and is not indicative of whether or not the particular techniques would otherwise come within the definition of "gene technology" in section 10 of the Act.

Item 6

Table item 1 of Schedule 1A of the Principal Regulations provides that the transfer of somatic cell nuclei (whether between cells of the same species or of different species) is not gene technology if it does not involve genetically modified material. Item [6] expands table item 1 to also provide that transfer of mitochondria, plastids, and nuclei other than from somatic cells, are not gene technology if they do not involve genetically modified material.

Item 7

Item [7] amends table item 11 of Schedule 1A of the Principal Regulations to specify techniques that involve introducing nucleic acids and nucleic acid analogues into an organism that are not gene technology. The status of nucleic acids that meet the definition of 'organism' in the Act, such as self-amplifying RNAs, would be unchanged by item [7].

Gene silencing techniques involving applying RNA to an organism to temporarily induce RNA interference continue to be excluded from the definition of "gene technology",

provided the specified criteria are met. This includes introducing small interfering RNAs, artificial microRNAs, short or long double-stranded RNAs and short hairpin RNAs, by any method.

Introducing mRNA to an organism is not gene technology if the introduction does not result in alteration of the genome sequence of the organism and cannot give rise to an infectious agent. The amended item does not restrict the delivery mechanism for introducing mRNA to an organism, for example as naked RNA or RNA encapsulated in a lipid nanoparticle. Examples of mRNA techniques that do not meet the specified criteria are: applying mRNAs encoding gene editing proteins that result in alteration of the organism's genome sequence; introducing self-amplifying mRNAs that can give rise to infectious agents.

Amended item 11 provides that introducing antisense oligonucleotides to an organism to modulate endogenous gene expression is not gene technology, provided the criteria are met. This includes application of morpholinos, splice switching oligonucleotides and DNA oligonucleotides that cannot be transcribed.

Items [8]-[10] – Organisms that are not GMOs

These items amend table items of Schedule 1 to the Principal Regulations, which supports regulation 5, listing organisms that are not GMOs for the purposes of the definition of "genetically modified organism" in the Act. This provides clarity about the status of these organisms, as understood within the context of the current state of technology. Listing organisms in Schedule 1 is not indicative of whether or not they meet parts (a) to (c) of the definition of "genetically modified organism" in the Act.

Items 8-9

Table item 6 of Schedule 1 to the Principal Regulations addresses the status of organisms that result from an exchange of DNA within a species. Items [8] and [9] amend table item 6 to clarify that this item only applies to micro-organisms, rather than any organism.

Item 10

Table item 10 of Schedule 1 to the Principal Regulations provides that an organism is not a GMO if, having previously been modified by gene technology, the organism no longer has the genetic modification or any traits that occurred because of gene technology. Some applications of gene technology result in epigenetic changes to organisms, for example, changes in methylation of genomic DNA or histone acetylation. To address the status of organisms with epigenetic modifications as a result of gene technology, item [10] amends table item 10 to specify that organisms that were modified by gene technology are not GMOs if the only remaining modifications and traits are epigenetic.

Part 2—Application and transitional provisions

Item [11]

This item provides for application and transitional provisions in relation to the amendments made to the Principal Regulations by Part 1 of this Schedule.

New regulation 45 provides that the amendment of paragraph 9(d), to reflect changes to chemicals regulation, applies, in relation to the Gene Technology Regulator seeking advice on a risk assessment and risk management plan or on matters relevant to the preparation of a risk assessment and risk management plan, from commencement.

New regulation 46 provides that the amendment of regulation 19, to specify when a committee member's or expert adviser's resignation takes effect, applies in relation to notices of resignation given to the Minister on or after commencement.

New regulation 47 provides that the amendment of regulation 20, to change requirements relating to the disclosure of interests by advisory committee members, applies in relation to committee meetings held from commencement. This applies even if the member made their disclosure prior to commencement.

New regulation 48 addresses the application of amendments of Schedule 1A of the Principal Regulations (techniques that are not gene technology), and so provides clarity as to whether particular organisms are GMOs for the purposes of the definition of "genetically modified organism" in section 10 of the Act. Where amendments of Schedule 1A have the effect that a technique ceased to be gene technology, regulation 48 clarifies the status after commencement of organisms modified by that technique prior to commencement and organisms inheriting traits that occurred because of application of that technique prior to commencement.

New regulation 49 addresses the application of amendments of Schedule 1 of the Principal Regulations (organisms that are not GMOs) as follows:

- If, prior to commencement, an organism was not a GMO because item 6 of Schedule 1 of the Principal Regulations applied to that organism and the amendments of item 6 have the effect that the item no longer applies to the organism, new subregulation 49(1) provides that the organism becomes a GMO on the day 12 months after the commencement day. This may be applicable if the organism is not a micro-organism.
- If the amendments of item 10 have the effect that item 10 newly applies to an organism to which item 10 did not previously apply, new subregulation 49(2) provides that the organism ceases to be a GMO from commencement. For example, this would be the case for a GMO with epigenetic modifications that occurred because of gene technology and with no other traits or modifications that occurred because of gene technology.

ATTACHMENT B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Gene Technology Amendment (Minor Measures) Regulations 2025

The *Gene Technology Amendment (Minor Measures) Regulations 2025* (the Regulations) are compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Disallowable Legislative Instrument

The Regulations are made under subsection 193(1) of the *Gene Technology Act 2000* (the Act). The purpose of the Regulations is to amend the *Gene Technology Regulations 2001* in order to:

- confer a new function on the Gene Technology Regulator, of making inspectors available to undertake inspections and audits of laboratories in Australia that hold poliovirus;
- clarify and update items on the lists of techniques that are not taken to be gene technology for the purposes of the Act, and organisms that are not taken to be GMOs for the purposes of the Act;
- update the list of agencies and authorities the Gene Technology Regulator must consult in relation to licence applications, risk assessments and risk management plans;
- specify when any resignation by a statutory advisory committee member or an expert advisers takes effect; and
- modernise requirements for managing potential conflicts of interest declared by statutory advisory committee members.

Human rights implications

This Disallowable Legislative Instrument does not engage any of the applicable rights or freedoms.

Conclusion

This Disallowable Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

Ged Kearney, Assistant Minister for Health and Aged Care and Parliamentary Secretary to the Minister for Health and Aged Care