



Gene Technology Amendment (Minor Measures) Regulations 2025

I, the Honourable Sam Mostyn AC, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 20 February 2025

Sam Mostyn AC
Governor-General

By Her Excellency's Command

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

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1 Name

This instrument is the *Gene Technology Amendment (Minor Measures) Regulations 2025*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is registered.	26 February 2025

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *Gene Technology Act 2000*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Gene Technology Regulations 2001

1 Regulation 5A

Repeal the regulation, substitute:

5A Functions of the Regulator

For the purposes of paragraph 27(1) of the Act, the Regulator has the following functions:

- (a) to make inspectors available to be appointed as inspectors under Division 7 of Part 3 of the *National Health Security Act 2007*;
- (b) to make inspectors available to undertake inspections and audits, in relation to the containment of poliovirus, of laboratories in Australia that hold poliovirus.

2 Paragraph 9(d)

Repeal the paragraph, substitute:

- (d) that part of the Department known as the Australian Industrial Chemicals Introduction Scheme;

3 Regulation 19

Before “A member”, insert “(1)”.

4 At the end of regulation 19

Add:

- (2) The resignation takes effect on the day the notice is received by the Minister or, if a later day is specified in the notice, on that later day.

5 Subregulation 20(4)

Repeal the subregulation, substitute:

- (4) A disclosure in relation to a matter by a member of the Committee under subregulation (2) must be recorded in the minutes of the meeting referred to in that subregulation.
- (5) Unless the Committee otherwise determines, the member:
 - (a) must not be present during any deliberation by the Committee on the matter; and
 - (b) must not take part in any decision of the Committee with respect to the matter.
- (6) For the purposes of making a determination under subregulation (5), the member:
 - (a) must not be present during any deliberation of the Committee for the purpose of making the determination; and
 - (b) must not take part in making the determination.

- (7) A determination under subregulation (5) must be recorded in the minutes of the meeting of the Committee.

6 Schedule 1A (table item 1)

Repeal the item, substitute:

- 1 Either of the following transfers, if the transfer does not involve genetically modified material:
- (a) nuclear transfer;
 - (b) transfer of plastids or mitochondria.

7 Schedule 1A (table item 11)

Repeal the item, substitute:

- 11 Introduction of nucleic acid or nucleic acid analogue into an organism, if:
- (a) the introduction of the nucleic acid or nucleic acid analogue does not result in an alteration of the organism's genome sequence; and
 - (b) the introduction of the nucleic acid or nucleic acid analogue cannot give rise to an infectious agent; and
 - (c) in the case of nucleic acid or nucleic acid analogue that is DNA—the DNA cannot be transcribed.

8 Schedule 1 (table item 6)

Omit "An organism", substitute "A micro-organism".

9 Schedule 1 (table item 6, paragraph (b))

Omit "vector", substitute "exchanged".

10 Schedule 1 (table item 10)

Omit "no longer present", substitute "either no longer present or are epigenetic".

Part 2—Application and transitional provisions

Gene Technology Regulations 2001

11 At the end of Part 8

Add:

Division 2—Amendments made by the Gene Technology Amendment (Minor Measures) Regulations 2025

44 Preliminary

In this Division:

amending regulations means the *Gene Technology Amendment (Minor Measures) Regulations 2025*.

commencement day means the day the amending regulations commence.

45 Risk assessments and risk management plans

Paragraph 9(d), as substituted by the amending regulations, applies in relation to the seeking of advice on or after the commencement day:

- (a) on a risk assessment and a risk management plan; or
- (b) on matters relevant to the preparation of a risk assessment and a risk management plan.

46 Resignation of committee member or expert adviser

The amendments of regulation 19 made by the amending regulations apply in relation to a notice of resignation given to the Minister on or after the commencement day.

47 Disclosure of interests by committee member

The amendment of regulation 20 made by the amending regulations applies in relation to a committee meeting held on or after the commencement day, regardless of whether the disclosure of interests, by a member of the committee in relation to a matter to be considered at that meeting, was made before, on or after the commencement day.

48 Techniques that are not gene technology

The amendments of Schedule 1A made by the amending regulations apply in relation to a technique on or after the commencement day, regardless of whether the technique was applied before, on or after that day.

Note: The effect of this regulation includes that an organism that was a GMO immediately before the commencement day may cease to be a GMO from when the amendments commence, even if:

- (a) a technique applied to modify the organism before the commencement day was gene technology at the time it was applied; or

- (b) the organism inherited a trait, from another organism, that occurred in that other organism because of a technique that was gene technology at the time it was applied.

49 Organisms that are not GMOs

- (1) The amendments of item 6 of Schedule 1 made by the amending regulations apply in relation to an organism on or after the day that is 12 months after the commencement day.

Note: The effect of this regulation includes that an organism that is not a GMO immediately before the day that is 12 months after the commencement day may start to be a GMO from 12 months after the amendments commence.

- (2) The amendment of item 10 of Schedule 1 made by the amending regulations applies in relation to an organism on or after the commencement day.

Note: The effect of this regulation includes that an organism that was a GMO immediately before the commencement day may cease to be a GMO from when the amendment commences.