



Overview – status of organisms modified using gene editing and other new technologies

This document has been prepared to assist regulated organisations to understand which new technologies, including gene editing techniques, result in genetically modified organisms (GMOs) that are regulated under the *Gene Technology Act 2000* (the Act). This document is not intended to be a comprehensive summary nor does it provide legal advice. Refer to the Act and Gene Technology Regulations 2001 (the Regulations) for an authoritative statement of the law. If you are unsure about how to meet your legal obligations, OGTR suggests you seek your own legal advice.

Recent legislative changes

As gene technology develops, Australia’s gene technology legislation requires updating to reflect scientific developments and to give users better clarity about their regulatory requirements. The Gene Technology Ministers’ Meeting agreed amendments to the Regulations which were made by the Governor-General on 20 February 2025 and came into effect on 26 February 2025¹. These amendments include changes to items in the lists of exclusions to the definitions of “gene technology” and “GMO”, which are summarised in this document. These amendments provide clarity about the status of the described techniques and organisms and are not indicative of whether or not the particular techniques or organisms would otherwise come within the definitions of “gene technology” and “GMO” in section 10 of the Act.

Organisms modified using SDN-1 are not GMOs

Schedule 1 of the Regulations lists organisms that are not GMOs for the purposes of the Act. Items on this list exclude organisms modified through unguided repair of site-directed nuclease (SDN) activity, also known as SDN-1 organisms, from regulation as GMOs. Unguided repair means that no nucleic acid template was added to cells to guide genome repair following SDN application. SDNs include, but are not limited to, CRISPR/Cas9, zinc finger nucleases, meganucleases and TALENs.

Site-directed nucleases can be applied in a variety of ways to produce SDN-1 organisms. Some of these methods generate GMOs in intermediate steps, and dealings with these GMOs will continue to require authorisation under the Act. Table 1 summarises the status of organisms with SDN-1 modifications, provided that the organisms have no other modifications from gene technology beyond those described in the table.

Some examples illustrating the status of organisms produced in the course of using SDN-1 are:

- An organism supplied with Cas9 protein and guide RNA/s in which an SDN-1 modification occurs is not a GMO.
- An organism expressing Cas9 and guide RNA/s from an expression cassette not integrated into the genome is a GMO while the expression cassette or its expressed products are present. If the expression cassette and its expressed products have degraded over time and only SDN-1 modifications remain, the organism is not a GMO.
- An organism with Cas9 and guide RNA transgenes integrated into its genome is a GMO, but those of its segregating offspring carrying an SDN-1 modification but lacking the Cas9 and gRNA transgenes are not GMOs.

¹ [The Gene Technology Amendment \(Minor Measures\) Regulations 2025](#)

Table 1: Status of organisms with SDN-1 modifications, by method of SDN application

	SDN protein applied (with or without sgRNA)	SDN expressed from a transgene that is only transiently present in the organism	SDN expressed from transgene integrated in the genome
Status of the initial organism modified by SDN-1	Not a GMO (Schedule 1 item 4)	GMO while transgene or its expressed products are present Not a GMO when transgene and expressed products have degraded (Schedule 1 items 4+10)	GMO
Status of offspring inheriting the SDN-1 modification	Not a GMO (Schedule 1 item 9(a))	Not a GMO (Schedule 1 item 9(b))	GMO if SDN transgene also inherited Not a GMO if no SDN transgene inherited (Schedule 1 item 9(b))

In each example, this status depends upon:

- no nucleic acid template being supplied to guide genome repair through homology-directed recombination, and
- the organism having no other modifications as a result of gene technology.

It is the responsibility of proponents to comply with the law and ensure that these requirements have been met.

SDN-1 organisms may be subject to regulation by other agencies, depending upon their characteristics and intended uses.

The legislative provisions referred to above do not exclude organisms modified using base editing or prime editing methods from regulation as GMOs, because the provisions are specific to enzymes with nuclease activity. Base editing and prime editing use disabled CRISPR/Cas9 coupled with other enzymatic domains to modify genes or genetic material, e.g. cytidine deaminase or adenosine deaminase.

Organisms modified using template-guided SDN techniques and ODM are GMOs

Schedule 1B, Organisms that are genetically modified organisms, provides that:

- organisms modified using oligonucleotide-directed mutagenesis are GMOs (**Schedule 1B item 1**)
- organisms modified using SDN techniques involving templates to guide repair of SDN action, also known as SDN-2 and SDN-3, are GMOs (**Schedule 1B item 2**).

In each case, the method used to modify the organism is central to determining whether or not the organism is a GMO. The number of resulting nucleotide changes, whether insertions or deletions, or whether the resulting nucleotide sequence may be found in sexually compatible species, is not a deciding factor.

Some RNA interference (RNAi) techniques are not gene technology

RNAi techniques involving directly applying RNAs to temporarily induce RNAi are listed as a technique that is not gene technology in **item 11 of Schedule 1A**. As a result, organisms modified using these techniques are not classified as GMOs.

The RNAs could be introduced to the organism by any method including, but not limited to:

- the organism taking up an externally applied RNA (e.g. by spraying with or dipping in an RNA solution)
- injecting RNA into the organism
- electroporation, and
- methods leading to the organism consuming material to which the RNA has been applied (e.g. insects consuming RNA by feeding on plant material sprayed with RNA).

To ensure that only short-lived RNAi techniques are excluded, this exclusion only applies if:

- the organism's genomic DNA sequence cannot be changed by the technique (this requirement can be met even if changes to genomic DNA methylation can occur), and
- the introduced RNA cannot lead to the production of infectious agents.

Provided the above requirements are met, the applied RNAs could potentially include small interfering RNAs, artificial microRNAs, short or long double-stranded RNAs and hairpin RNAs, with sequence of any origin. It is the responsibility of proponents to comply with the law and ensure that the requirements above have been met.

Item 11 of Schedule 1A does not change the status of organisms to which other RNAi techniques have been applied, e.g. where an organism is stably transformed with a transgene able to express RNA that can induce gene silencing, this remains a GMO.

Product regulators such as the Australian Pesticides and Veterinary Medicines Authority or the Therapeutic Goods Administration may have requirements in relation to these techniques.

Other techniques involving introduction of nucleic acids or nucleic acid analogues

In February 2025, item 11 of Schedule 1A was amended to address a broader set of techniques involving introduction of nucleic acids to an organism. Amended item 11 provides that introduction of nucleic acid or nucleic acid analogue into an organism is not gene technology if all of the following apply:

- it does not result in an alteration of the organism's genome sequence
- it cannot give rise to an infectious agent, and
- in the case of introduced DNA, the DNA cannot be transcribed.

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

Amended item 11 also addresses techniques that involve introducing mRNA to an organism that meet the criteria above. This is the case regardless of 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, and which are gene technology, 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.

Additionally, there are nucleic acids that meet the definition of 'organism' in the Act, such as self-amplifying RNAs. Where they are made using gene technology, these organisms are GMOs and are regulated under the Act.

Organisms derived from GMOs but with no traits from gene technology, or only epigenetic modifications

Consistent with the definition of a GMO in the Act the Regulations clarify the non-GMO status of organisms derived from GMOs but which do not possess traits as a result of gene technology. These organisms are:

- offspring of GMOs that have not inherited traits that occurred in a parent because of gene technology, commonly referred to as null segregants (**Schedule 1 item 8**)
- organisms temporarily modified using gene technology but which have lost all traits (e.g. transgenes, products expressed from transgenes) that occurred because of gene technology (**Schedule 1 item 10**).

In addition, amendments in February 2025 to Schedule 1 item 10 specify that organisms that were modified using gene technology, but which only have epigenetic changes remaining, are not GMOs.

Modifications produced using SDN techniques are traits that occurred because of gene technology, so item 8 does not exclude these organisms from being GMOs. However, other items described above do exclude SDN-1 organisms from regulation.

Other recent amendments

In addition to the amendments to Schedule 1A item 11 and Schedule 1 item 10 described above, the February 2025 amendments to the Regulations introduced the following changes:

- item 1 of Schedule 1A was expanded to specify that transfer of nuclei (whether or not from somatic cells), plastids and mitochondria are not gene technology if they do not involve genetically modified material. This applies to transfer between cells of the same species and of different species.
- item 6 of Schedule 1, which relates to organisms resulting from exchange of DNA within a species, was changed to clarify that this item only applies to micro-organisms. This amendment applies from 26 February 2026.