This document is to be used by biosafety applicants to assist with determining the type of dealing that may be involved in their project.

This document will need to be submitted with your biosafety application and will be reviewed by the JCU Institutional Biosafety Committee.

Read:

* The “definitions and important information” section before you start the application
* The “points to consider” and instructions on page 10
* The application begins on page 16

AS/NZS 2243.3:2022 is referred to within this document. To access the document, go to the JCU Library page, databases, Standards Australia.

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## Definitions & Important information

**A genetically modified organism (GMO) is:**

* a plant, animal or other organism that has been modified using **gene technology**
* an organism that has inherited modified traits from a GMO.

**Gene technology** (also known as genetic engineering or genetic modification) **is any technique for the modification of genes or genetic material.**

When plants, animals and other organisms are changed using gene technology they are known as genetically modified organisms (GMOs). When gene technology is used to create a GMO the use of that organism is regulated by the Gene Technology Regulator to protect people and the environment.

**A GMO dealing is an interaction with a GMO. The Gene Technology Act 2000 defines a dealing as meaning:**

* conduct experiments with the GMO
* make, develop, produce or manufacture the GMO
* breed the GMO
* propagate the GMO
* use the GMO in the course of manufacture of a thing that is not the GMO
* grow, raise or culture the GMO
* import the GMO
* transport the GMO
* dispose of the GMO
* possess, supply or use the GMO for the purposes of, or in the course of, any of the above.

**Definitions of the different types of GMO dealings are provided below.**

## Exempt dealings

Exempt dealings are dealings with GMOs that pose a very low risk. They cannot involve any release of a GMO into the environment, such as field trials or commercial releases.

Schedule 2 of the [Gene Technology Regulations 2001](https://www.legislation.gov.au/Details/F2020C00651) lists dealings considered exempt. The list is updated during [legislative reviews of the Regulations](https://www.ogtr.gov.au/node/30). Typically, this is due to a submission from an Institutional Biosecurity Committee (IBC).

Exempt dealings do not need a licence if the activity stays within specified criteria. Generally, an IBC will confirm if a dealing is exempt.

Exempt dealings are not listed on the GMO record.

## Notifiable low risk dealings (NLRD)

A notifiable low risk dealing (NLRD) is an activity with GMOs that is:

* undertaken in containment, in a facility certified by the Regulator or approved in writing by the Regulator
* assessed as posing low risk to the health and safety of people and the environment provided certain risk management conditions are met.

Schedule 3 of the [Gene Technology Regulations 2001](https://www.legislation.gov.au/Details/F2020C00957) (the Regulations) specifies the types of dealings with GMOs classified as NLRDs.

An [Institutional Biosafety Committee (IBC)](https://www.jcu.edu.au/work-health-and-safety/occupational-hygiene/biosafety-and-quarantine) must assess a dealing as an NLRD before it can be undertaken.

## Dealings not involving intentional release (DNIR)

A DNIR is a dealing not involving the intentional release of a GMO into the environment. These are dealings with GMOs in containment which do not meet the criteria for classification as exempt dealings or notifiable low risk dealings (NLRDs).

Dealings with a GMO licensed as a DNIR:

* must not involve release into the environment
* must be licensed by the Regulator.

Schedule 3, Part 3 of the Regulations describes which dealings with GMOs cannot be authorised by NLRDs. These dealings need to be authorised by DNIR licences.

DNIRs often involve genetically modified, disease-causing (pathogenic) organisms, or GMOs containing higher risk genes from pathogens or genes that:

* encode toxins
* confer a cancer-causing (oncogenic) modification or immuno-modulatory effect (changing the immune system).

## Dealings involving intentional release (DIR)

A DIR is a dealing involving the intentional release of GMOs. These are dealings with GMOs which take place outside of containment. Most DIR licences issued have been for:

* experimental field trials of GM plants (limited and controlled releases)
* general/commercial releases of GM plants.

Some DIR licences have been issued for GMOs for medical or veterinary use, either for trial (limited and controlled release) or general/commercial release. The release of GM animals would also require a DIR licence.

## Inadvertent dealings

It is possible to come into possession of a GMO without realising or intending to. If this happens, all further dealings with the GMO, including destruction, require an authorisation.

The Act provides for inadvertent dealings licences to facilitate the safe and legal disposal of a GMO.

The Regulator may treat a person as having made an inadvertent dealings application under section 40A of the Act, if:

* the Regulator is satisfied that the person came into possession of a GMO inadvertently.
* the person agrees.

A person may also apply for a licence under section 40 of the Act in respect of an inadvertent dealing.

The Regulator may issue a temporary licence to the person. This is so the person can dispose of the GMO in a manner which protects the health and safety of people and the environment. Inadvertent dealings applications follow a simpler process than other application types.

## Clinical trials

The type of approval required for a trial depends on the nature of the GMO and its likely fate once introduced into the trial participant. Clinical trials where patient cells are removed, genetically modified and replaced may not need a licence if they meet specific requirements.

Clinical trials involving any other type of GMO will need a licence. If participants can shed, excrete or transmit the GMO, the trial needs a [DIR licence](https://www.ogtr.gov.au/node/525). Otherwise, the trial needs a [DNIR licence](https://www.ogtr.gov.au/node/526).

## Viral vectors

Dealings with viral vectors can be classified in the DNIR, NLRD and Exempt categories.

The Regulator also has [guidance for IBCs assessing NLRDs involving retroviral (including lentiviral) vectors](https://ogtr.govcms.gov.au/node/303) ([**refer to Appendix 1**](#_Appendix_1:_Guidance)), particularly in assessing whether:

* persons have the appropriate training and experience to undertake the dealings.
* the facilities are appropriate for the dealings.

## Gene editing and RNA interference

Whether or not organisms modified using gene editing or RNA interference are GMOs depends upon the specific technique used ([**refer to Appendix 2**](#_Appendix_2:_Overview)). The Regulator has developed an [overview of the status of organisms modified using gene editing and other new technologies.](https://www.ogtr.gov.au/resources/publications/overview-status-organisms-modified-using-gene-editing-and-other-new-technologies)

## Gene drives

Gene drives are genetic elements that are favoured for inheritance. An organism that contains a gene drive due to gene technology will be a GMO. It will be subject to regulation under the Act.

Contained dealings with GMOs containing functional gene drives need a [DNIR licence](https://www.ogtr.gov.au/node/526).

Dealings with viral vectors that can change an organism to produce an engineered gene drive also need a [DNIR licence](https://www.ogtr.gov.au/node/526).

**Points to consider before completing this form and commencing work:**

1. Will you be working with gene technology? Refer to **definitions above.**
2. Will you be undertaking experiments to modify the genome of an organism using technologies, such as oligonucleotide-directed mutagenesis (also known as site-directed mutagenesis), viral vectors and site-directed nucleases (SDNs), including CRISPR/Cas9?
3. **Refer** to [**table 1**](#_Table_1:_Techniques)**,** [**table 2**](#_Table_2:_Organisms) **&** [**table 3**](#_Table_3:_Organisms) to verify if your project dealing is considered a GMO **prior** to completing this application.
4. Will your project be considered as[**exempt**](#_Part_A_:)**, a** [**notifiable low risk dealing**](#_Part_B:_Notifiable)or a[**licensed dealing?**](#_Part_C:_Dealings)If your project is a licensed dealing then willyou need a dealings not involving intentional release **(DNIR)** license or a dealings involving intentional release **(DIR)** license, both of which are described above.
5. If you are planning to use viral vectors, whether retroviral, or non-retroviral, in a GMO dealing then refer to [**Appendix 1**](#_Appendix_1:_Guidance), which provides a useful guide to the type of application and approvals you will require to undertake these studies.
6. If you are using site-directed nuclease (SDN) technology, including CRISPR-Cas9 in your dealings, then refer to the following definitions, as not all usage of SDN technology will result in a GMO: **(more details can be found in** [**Appendix 2**](#_Appendix_2:_Overview)**)**
7. Consider what **containment requirements and facility certifications** are needed for your proposed project (**more details can be found in** [**Appendix 3**](#_Appendix_3:_Containment)**)**.

**Instructions:**

1. If your proposed project involves **any of the modifications outlined in** [**Table 3**](#_Table_3:_Organisms)(see **page 11** of this form)then this application form **MUST** be completed and **submitted to (and approved by) the James Cook University Institutional Biosafety Committee (IBC) PRIOR to commencement of any GMO Dealing undertaken by university personnel or by personnel from other institutions who are working in JCU premises.**
2. If completing this form, then you **MUST** fill in the[**Preliminary information section.**](#_Preliminary_Information) **Then complete either part** [**A**](#_Part_A_:)**,** [**B**](#_Part_B:_Notifiable) **or** [**C**](#_Part_C:_Dealings)**, depending on whether you consider your project and GMO dealings to be** [**A)** Exempt](#_Part_A_:),[**B)** Notifiable Low Risk Dealing (NLRD)](#_Part_B:_Notifiable)or[**C)** Licensed Dealing (DNIR/DIR)](#_Part_C:_Dealings)**.**
3. **Refer to the** [**GMO Dealing Decision Flowchart**](#_GMO_Dealing_Decision) **on the next page to help with your decision-making process.**
4. The **final decision** relating to the **type of license required for your work** will be confirmed following assessment of your application **by at least two (2) members of the IBC.**

## GMO Dealing Decision Flowchart

# **Table 1:** Techniques that are **not** gene technology

*This table lists technologies that are* ***not*** *considered gene technology, initially refer to this table to determine whether your dealings will involve one of these excluded technologies, as per Schedule 1A, Gene Technology Regulations 2001 Statutory Rules No, 106, 2001.* [*https://www.legislation.gov.au/Details/F2020C00957*](https://www.legislation.gov.au/Details/F2020C00957)*.*

|  |  |
| --- | --- |
| Techniques that are not gene technology | |
| **Item** | **Description of technique** |
| 1 | Somatic cell nuclear transfer, if the transfer does not involve genetically modified material. |
| 2 | Electromagnetic radiation induced mutagenesis. |
| 3 | Particle radiation induced mutagenesis. |
| 4 | Chemical induced mutagenesis. |
| 5 | Fusion of animal cells, or human cells, if the fused cells are unable to form a viable whole animal or human. |
| 6 | Protoplast fusion, including fusion of plant protoplasts. |
| 7 | Embryo rescue. |
| 8 | *In vitro* fertilisation. |
| 9 | Zygote implantation. |
| 10 | A natural process, if the process does not involve genetically modified material.  Examples: *Examples of natural processes include conjugation, transduction, transformation and transposon mutagenesis.* |
| 11 | Introduction of RNA into an organism, if:  (a) the RNA cannot be translated into a polypeptide; and  (b) the introduction of the RNA cannot result in an alteration of the organism’s genome sequence; and  (c) the introduction of the RNA cannot give rise to an infectious agent.  ***Further explanation:***  ***RNAi*** *techniques involving directly applying RNAs to temporarily induce RNAi are listed as a technique that is* ***not*** *gene technology. As a result, organisms modified using these techniques are* ***not*** *classified as GMOs.*  *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 be translated into a protein******or 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.*  *Item 11 of this table does not change the status of organisms to which other RNAi techniques have been applied, e.g. where an organism is stably or transiently transformed with a transgene able to express RNA that can induce gene silencing, this remains a GMO.* |

# **Table 2:** Organisms that are **not** genetically modified organisms (GMOs)

*This table**outlines organisms that are* ***not considered GMOs,*** *as per Schedule 1, Gene Technology Regulations 2001 Statutory Rules No, 106, 2001.* [*https://www.legislation.gov.au/Details/F2020C00957*](https://www.legislation.gov.au/Details/F2020C00957)

|  |  |
| --- | --- |
| Organisms that are not GMOs | |
| *An organism is not a genetically modified organism if:**(a) one or more items in this table applies to the organism; and**(b) the organism has not been modified by gene technology except for any modifications described in those items; and**(c) the organism has not inherited any traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology, except as described in item 9 of this table**(d) none of the items in Table 3 below applies to the organism.* | |
| **Item** | **Description of organism** |
| 2 | A whole animal, or a human being, modified by the **introduction of naked recombinant nucleic acid (such as a DNA vaccine)** into its **somatic cells**, if the introduced nucleic acid is incapable of giving rise to infectious agents. |
| 3 | Naked plasmid DNA that is **incapable** of giving rise to infectious agents when introduced into a host cell. |
| 4 | An organism modified by repair of single‑strand or double‑strand breaks of genomic DNA induced by a **site-directed nuclease (SDN),** if a nucleic acid template was **not added to** **guide homology-directed repair.**  *Organisms modified through* ***unguided repair of site-directed nuclease (SDN) activity****, also known as SDN-1 organisms, are* ***excluded 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.*  ***Some examples:***   * *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.*   ***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.*   ***NOTE:***   * *SDN-2 genome editing involves a template-guided repair (homology-directed repair) of a targeted double-strand break using a sequence donor, typically short single-stranded DNA (short template with one or several nucleotide difference). The donor is recognised as a repair template, allowing the introduction of the mutation(s) at the target site(s). SDN-2 modifications* ***are considered as GMOs.*** * *SDN-3 genome editing Involves a template-guided repair (homology-directed repair) of a targeted double-strand break using a sequence donor, typically double-stranded DNA containing an entire gene or an even longer genetic element(s). The donor is recognised as a repair template, allowing the introduction of the gene or genetic element(s) at the target site. SDN-3 modifications* ***are considered as GMOs.***   *Definition modified from* |
| 6 | An organism that results from an exchange of DNA if:  (a) the donor species is also the host species; and  (b) the vector DNA does not contain any heterologous DNA. |
| 7 | An organism that results from an exchange of DNA between the donor species and the host species if:  (a) such exchange can occur by naturally occurring processes; and  (b) the donor species and the host species are micro‑organisms that:  (i) satisfy the criteria in [AS/NZS 2243.3:2022 for classification as Risk Group 1](https://au.i2.saiglobal.com/management/display/index/0/54419/-/860cd61dc45e5f3e40e63c4990224026); and  (ii) are known to exchange nucleic acid by a natural physiological process; and  (c) the vector used in the exchange does not contain heterologous DNA from any organism other than an organism that is involved in the exchange. |
| 8 | An organism that is descended from a genetically modified organism (the ***initial organism***), if none of the traits it has inherited from the initial organism are traits that occurred in the initial organism because of gene technology. |
| 9 | An organism that has inherited particular traits from an organism (the ***initial organism***), being traits that occurred in the initial organism because of gene technology, if:  (a) the initial organism was not a genetically modified organism; or  (b) all such inherited traits are traits that occurred in the initial organism as a result of a modification described in an item in this Schedule. |
| 10 | An organism that was modified by gene technology but in which the modification, and any traits that occurred because of gene technology, are no longer present. |
| 11 | *Agrobacterium radiobacter* strain K1026. |
| 12 | *Pasteurella multocida* strain PMP1. |

# **Table 3:** Organisms that **are** genetically modified organisms (GMOs)

*This table**outlines* ***organisms that are considered GMOs****, as per Schedule 1B, Gene Technology Regulations 2001 Statutory Rules No, 106, 2001.* [*https://www.legislation.gov.au/Details/F2020C00957*](https://www.legislation.gov.au/Details/F2020C00957)

|  |  |
| --- | --- |
| Organisms that are GMOs | |
| *An organism is a genetically modified organism if an item in this table applies to the organism.* | |
| **Item** | **Description of organism** |
| 1 | An organism that has had its genome modified by oligonucleotide directed mutagenesis |
| 2 | An organism modified by repair of single strand or double strand breaks of genomic DNA induced by a site directed nuclease, if a nucleic acid template was added to guide homology directed repair |

## Preliminary Information (*You MUST complete this section*)

|  |
| --- |
| **Instructions:**  This application form must be completed and submitted to the James Cook University Institutional Biosafety Committee (IBC) for all **A)** **Exempt**, **B)** **Notifiable Low Risk (NLRD)** or **C)** **Licenced (DNIR/DIR)** GMO dealings undertaken by university personnel or undertaken by personnel from other institutions who are working in JCU premises.  Complete the *Preliminary information section*, then complete the relevant sections for the type of GMO dealings you propose to undertake:   * [**Part A**](#_Part_A:_Dealings) for exempt dealings (dealings exempt from licencing) * [**Part B**](#_Part_B:_Notifiable) for notifiable low risk dealings (NLRDs) * [**Part C**](#_Part_C:_Dealings) for licenced dealings (DNIRs)   Ensure you have obtained all required signatures and submit completed forms in **an electronic** format to: [biosafety@jcu.edu.au](mailto:biosafety@jcu.edu.au)  An electronic document with electronic signature is preferred. |

|  |  |  |
| --- | --- | --- |
| IBC use | IBC Dealing ID |  |

|  |  |  |
| --- | --- | --- |
| Preliminary information | | |
| **Institution responsible for dealing** This will be the primary employing institution of the Project Supervisor |  | |
| **Institutional Biosafety Committee** | James Cook University Institutional Biosafety Committee | |
| **Is this dealing reviewed/authorised by another IBC?** | Yes  No If yes, complete following details | |
| **Other IBC name** |  |
| **Dealing ID allocated by other IBC** |  |
| **Does this application replace another approved dealing?** | Yes  No If yes, complete following details | |
| **IBC Dealing Identifier number or**  **OGTR NLRD Identifier number** |  |
| **Category of the dealing being replaced**  leave blank if this application does not replace another dealing | Exempt  PC1 NLRD PC2 NLRD  PC3 NLRD DNIR |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Person responsible for dealing | | | | |
| **Project supervisor name** | |  | | |
| **Project Supervisor’s University ID** | |  | | |
| **Primary Employing Institution of Project Supervisor (if not James Cook University)** | |  | | |
| **Email address** | |  | | |
| **Telephone** | |  | | |
| **Discipline or business unit** | |  | | |
| **Has the project supervisor previously submitted a GMO dealing application to this IBC?** | | Yes  No If no, please provide a brief one-page resume as an attachment outlining relevant experience and qualifications in relation to GMO work. | | |
| Project title *For notifiable low risk dealings (NLRDs) and licenced dealings, this title will be published in the* [*OGTR GMO Record*](https://www.ogtr.gov.au/gmo-dealings)*, along with the dealing commencement date, and dealing type(s).* | | | | |
|  | | | | |
| GMO Dealing Type *(e.g. exempt, NLRD)* *Irrespective of the dealing type you must complete either* [*Part A*](#_Part_A_:)*,* [*Part B*](#_Part_B:_Notifiable) *or* [*Part C*](#_Part_C:_Dealings) *of this document in addition to this preliminary information. If the dealing requires a license (Part C), then you need to determine if your work includes Dealings not involving intentional release (DNIR) or Dealings involving intentional release (DIR). A* [*DNIR*](https://www.ogtr.gov.au/apply-gmo-approval/apply-dnir-licence) *or* [*DIR*](https://www.ogtr.gov.au/apply-gmo-approval/apply-dir-licence#apply-for-a-licence) *license application will also need to be completed* ***in consultation with the JCU IBC.*** | | | | |
|  | | | | |
| **Facilities to be used**  *All facilities to be used, including places of storage, must be listed in your application.*  *Storage of some PC1 and PC2 GMOs outside of a certified facility is permitted, but the location must be approved by the IBC. Unauthorised storage of GMOs is an offence under the Act.*  *NOTE: For dealings with Risk Group 2 GM microorganisms that may generate aerosols – the facility must contain a Class II biosafety cabinet. Please note use of a BSCII in the experiments/aspects box.* | | | | |
|  | **Facility 1** | | **Facility 2** | **Facility 3** |
| **Organisation** |  | |  |  |
| **OGTR Certification No.** |  | |  |  |
| **Room Number(s)** |  | |  |  |
| **Building** |  | |  |  |
| **Class of Facility (PC1, PC2 PC3)** |  | |  |  |
| **Facility Contact** |  | |  |  |
| **Facility Contact Details** | Email | | Email | Email |
| **Experiments/aspects of dealing (including storage) in this facility** |  | |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Personnel and Training | | | |
| *The IBC must assess whether the persons or categories of persons have appropriate training and experience to undertake the dealing. This includes persons beyond the persons conducting the research, such as persons involved in importation, transportation and disposal of GMOs.*  *Indemnification of University personnel requires that the JCU IBC has a record of all persons undertaking the dealing****.*** | | | |
| **Indicate the categories of persons that will be involved with the dealing and list the name and ID for persons known at the time of writing this application.**  *Additional persons can be added later as they become known/involved with the dealing* | | | |
| **Classes of Persons** | | | **Name(s) and JCU ID number** *(JCXXXXXX)* |
| Principal Investigator | | |  |
| Research Staff | | |  |
| Postgraduate Students | | |  |
| Honours/undergraduate student | | |  |
| Visitor (researcher from another organisation) | | |  |
| Facility staff *(only uncheck if facility staff will not deal with GMOs)* | | | *Not required* |
| Transport personnel *(e.g. couriers, only uncheck if GMOs will not be transported by an external contractor)* | | | *Not required* |
| Waste collection service provider, *only uncheck if viable GMOs will not be disposed of)* | | | *Not required* |
| **Have all personnel named above read and understood the following training requirements for dealing with GMOs**  *It is the responsibility of the Principal Investigator to ensure that all listed personnel have read and understood all of the Guidelines that apply to the dealings they are proposing to undertake or will engage external persons to undertake. For example, personnel should read and understand parts 1.2.1 & 1.2.3 of the TSD Guidelines if they will be transporting PC2 GM animal to another facility or providing GMOs to a courier for transport.*  *Personnel commencing work on this dealing later must be trained and the IBC notified prior to commencing work on the dealing.* | | | |
| Laboratory/facility site-specific induction(s) | | | Yes No |
| [Biosafety Training and test](https://learn.jcu.edu.au/ultra/organizations/_17500_1/cl/outline) | | | Yes No |
| [Guidelines for the Transport, storage and Disposal of GMOs](https://www.ogtr.gov.au/resources/publications/guidelines-transport-storage-and-disposal-gmos)  *All sections relevant to the physical containment (PC) level and type of organisms in the application.* | | | Yes No |
| [National Framework of Ethical Principles in Gene Technology](https://www.ogtr.gov.au/sites/default/files/files/2021-07/national_framework_of_ethical_principles.pdf)  *Part 5.1 Ethical principles in gene technology (Pages 10-11).* | | | Yes No |
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| **Risk assessment and management** | | | |
| **Benefits of the work** (a brief statement in plain English) | | | |
|  | | | |
| **Describe the risks the proposed GMO dealings pose to the health and safety of people and the environment.** | | | |
|  | | | |
| **Describe the possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (ie the risk) from an unintentional release of the GMO(s).** (Include relevant riskware risk assessments when you email this application). | | | |
|  | | | |
| **Please indicate the relevant Risk Group(s) (as per ASNZS 2243:3:2022) for all micro-organisms involved in this dealing.** Select all that apply. | | No microorganisms involved in this dealing  Risk Group 1 micro-organisms involved in this dealing  Risk Group 2 micro-organisms involved in this dealing  Risk Group 3 micro-organisms involved in this dealing  Risk Group 4 micro-organisms involved in this dealing | |

***NOTE:*** *Microorganism risk groups (****Examples of microorganisms according to risk groups 2, 3 and 4 are available in clauses 3.2 – 3.7*** in [AS/NZS 2243.3:2022 Safety in Laboratories Part 3 Microbiological safety and containment](https://au.i2.saiglobal.com/management/display/index/0/54419/-/860cd61dc45e5f3e40e63c4990224026)). This document can be accessed by going through the JCU Library website, databases, Standards Australia.

***Risk Group 1*** *(low individual and community risk) - a microorganism that is unlikely to cause human, plant or animal disease.*

***Risk Group 2*** *(moderate individual risk, limited community risk) - a pathogen that can cause human, plant or animal disease, but is unlikely to be a serious hazard to laboratory workers, the community, livestock, or the environment; laboratory exposures may cause serious infection, but effective treatment and preventative measures are available, and the risk of spread is limited.*

***Risk Group 3*** *(high individual risk, limited community risk) - a pathogen that usually causes serious human or animal disease and may present a serious hazard to laboratory workers. It could present a risk if spread in the community, but there is usually effective preventative measures or treatment available.*

***Risk Group 4*** *(high individual and community risk) - a pathogen that usually produces life-threatening human or animal disease, represents a serious hazard to laboratory workers, and is readily transmissible from one individual to another. Effective treatment and preventative measures are not usually available.*

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| Comments for the JCU IBC |
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| Project Supervisor Declaration | | | |
| **Please initial** (*do not mark with tick or cross*) each of the following statements to indicate that you understand your responsibilities when dealing with GMOs and then sign the application form. | | | |
| I have read, considered and understand my responsibilities under the Gene Technology Act 2000 and agree to undertake the GMO dealing outlined in this application in accordance with the relevant Office of the Gene Technology Regulator guidelines and regulations (including, but not limited to all disposal, transport and storage). <http://www.ogtr.gov.au/> | | |  |
| I am aware of my responsibilities in relation to ensuring that any personnel conducting this work are appropriately trained and are aware of and follow the relevant guidelines and regulations. | | |  |
| I have considered the potential risks that the conduct of this dealing could pose to people and/or the environment and will implement appropriate actions and precautions to minimise these risks. | | |  |
| Where a GMO is received from sources outside the institution responsible for the project, I will take steps to confirm its identity. | | |  |
| In the event of an unintentional release of GMOs I am aware that I must put into place the appropriate responses to contain the release and I will inform the IBC as soon as practicable of any incidents, accidents or unintentional releases involving GMOs. | | |  |
| I am aware that breaches of the legislation are serious matters and that penalties could include loss of OGTR Accreditation status for the organisation, imprisonment and/or substantial fines. | | |  |
| I confirm that all personnel named in this application have read and understood the requirements for transporting, storing and disposing of GMOs, and the behavioral requirements for working in OGTR certified facilities. | | |  |
| ***Project Supervisor Name*** | ***Pr***o***ject Supervisor Signature*** | ***Date*** | |

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| Facility Manager Declaration (if applicable) | | | | | |
| As Facility Manager I have been informed of the nature of and risks involved with this GMO dealing and after consideration of them, I hereby consent to the work being performed in the listed facility.  I will ensure that the appropriate safety procedures are followed and that personnel are appropriately trained prior to undertaking work in the listed facility.  In the event of an unintentional release of GMOs I am aware that I must put into place the appropriate responses to contain the release and I will inform the IBC as soon as practicable of any incidents, accidents or unintentional releases involving GMOs. | | | | | |
| ***Facility 1 Facility Manager Name*** | | | ***Signature*** | | ***Date*** |
| ***Facility 2 Facility Manager Name*** | | | ***Signature*** | | ***Date*** |
| ***Facility 3 Facility Manager Name*** | | | ***Signature*** | | ***Date*** |
|  |  | |  | |  |
| Head of Discipline Declaration | | | | | |
| As the Senior Manager responsible for the research activities of the project supervisor, I have been informed of the nature of and risks involved with this GMO dealing and after consideration of them, I hereby consent to the work. | | | | | |
| ***Head of Discipline Name*** | | ***Signature*** | | ***Date*** | |

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| Dean of College Certification | | |
| As the Senior Manager responsible for the research activities of the project supervisor, I have been informed of the nature of and risks involved with this GMO dealing and after consideration of them, I hereby consent to the work. | | |
| ***Dean of College Name \*(or delegate)*** | ***Signature*** | ***Date*** |

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# Part A: Dealings exempt from licensing (**Exempt dealings**)

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| A(i) Type of exempt dealing | | |
| A dealing, in relation to a GMO, is an exempt dealing if:   * it is a dealing of a kind mentioned in this table; and * it does not involve a genetic modification other than a modification described in this table; and * it does not involve an intentional release of the GMO into the environment.   Important definition(s):  **Advantage**, in relation to an organism that is genetically modified, means a superior ability in its modified form, relative to the unmodified parent organism, to survive, reproduce or otherwise contribute to the gene pool.  **non-conjugative plasmid** means a plasmid that is not self-transmissible. | | |
| **Select all that apply** | **Item** | **Description of dealing** |
|  | 2 | A dealing with a genetically modified *Caenorhabditis elegans*, unless:  (a) an *advantage* is conferred on the animal by the genetic modification; or  (b) as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent. |
|  | 3 | A dealing with an animal into which genetically modified somatic cells have been introduced, if:  (a) the somatic cells are not capable of giving rise to infectious agents as a result of the genetic modification; and  (b) the animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells. |
|  | 3A | A dealing with an animal whose somatic cells have been genetically modified *in vivo* by a replication defective viral vector, if:  (a) the *in vivo* modification occurred as part of a previous dealing; and  (b) the replication defective viral vector is no longer in the animal; and  (c) no germ line cells have been genetically modified; and  (d) the somatic cells cannot give rise to infectious agents as a result of the genetic modification; and  (e) the animal is not infected with a virus that can recombine with the genetically modified nucleic acid in the somatic cells of the animal. |
|  | 4 | **NOTE: ALSO COMPLETE SECTION A(ii)**  (1) Subject to subitem (2), a dealing involving a host/vector system mentioned in table A(ii) below and producing no more than 25 litres of GMO culture in each vessel containing the resultant culture.  (2) The donor nucleic acid:  (a) must meet either of the following requirements:  (i) it must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy:  (A) human beings; or  (B) animals; or  (C) plants; or  (D) fungi;  (ii) it must be characterised and the information derived from its characterisation show that it is unlikely to increase the capacity of the host or vector to cause harm; and  *Example: Donor nucleic acid would not comply with subparagraph (ii) if its characterisation shows that, in relation to the capacity of the host or vector to cause harm, it:*  *(a) provides an advantage; or*  *(b) adds a potential host species or mode of transmission; or*  *(c) increases its virulence, pathogenicity or transmissibility.*  (b) must not code for a toxin with an LD50 of less than 100 micrograms per kilogram; and  (c) must not code for a toxin with an LD50 of 100 micrograms per kilogram or more, if the intention is to express the toxin at high levels; and  (d) must not be uncharacterised nucleic acid from a toxin producing organism; and  (e) if the donor nucleic acid includes a viral sequence—cannot give rise to infectious agents when introduced into any potential host species, without additional non host genes or gene products that:  (i) are not available in the host cell into which the nucleic acid is introduced as part of the dealing; and  (ii) will not become available during the dealing; and  (f) if the donor nucleic acid includes a viral sequence cannot restore replication competence to the vector. |
|  | 5 | **NOTE: ALSO COMPLETE SECTION A(ii)**  A dealing involving shotgun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in items 1 to 6 of table A(ii) below, if the donor nucleic acid is not derived from either:  (a) a pathogen; or  (b) a toxin‑producing organism. |

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| A(ii) Exempt hosts and vectors - only complete this section if exempt [4 & 5] dealing is selected in Part A(i) | | | |
| *A reference to a* ***host/vector system*** *mentioned is a reference to any of the following:*  *(a) a system involving a host mentioned in column 2 of an item of this table and a vector mentioned in column 3 of this table*  *(b) a non-vector system involving a host mentioned in column 2 of this table*  *(c) a system involving a GMO mentioned as a vector in column 3 of an item of this table (except item 7), without a host.* | | | |
| For Exempt dealings only - select all hosts and vectors that apply ***from the list below*** | | | |
| Item | Column 1: Host Class | Column 2: Host (select all that apply) | Column 3: Vectors (select all that apply) |
| 1 | Bacteria | *Escherichia coli* K12, *E. coli* B, *E. coli* C or *E. coli* Nissle 1917—any derivative that does not contain:   * 1. generalised transducing phages; or   2. genes able to complement the conjugation defect in a non‑conjugative plasmid | non‑conjugative plasmids;  lambda bacteriophage;  lambdoid bacteriophage;  Fd, F1 or M13 bacteriophage |
| 2 | Bacteria | *Bacillus—*asporogenic strains of the following species with a reversion frequency of less than 10–7:  (a) *B. amyloliquefaciens*;  (b) *B. licheniformis*;  (c) *B. pumilus*;  (d) *B. subtilis*;  (e) *B. thuringiensis* | non‑conjugative plasmids;  other plasmids and phages whose host range does not include *B. cereus*, *B. anthracis*or any other pathogenic strain of *Bacillus* |
| 3 | Bacteria | Pseudomonas putida strain KT2440 | Non‑conjugative plasmids |
| 4 | Bacteria | The following *Streptomyces* species:  (a) *S. aureofaciens*;  (b) *S. coelicolor*;  (c) *S. cyaneus*;  (d) *S. griseus*;  (e) *S. lividans*;  (f) *S. parvulus*;  (g) *S. rimosus*;  (h) *S. venezuelae* | non‑conjugative plasmids;  plasmids SCP2, SLP1, SLP2, pIJ101 and derivatives;  actinophage phi C31 and derivatives |
| 5 | Bacteria | Any of the following:  (a) *Agrobacterium radiobacter*;  (b) *Agrobacterium rhizogenes* (disarmed strains only);  (c) *Agrobacterium tumefaciens* (disarmed strains only) | Disarmed Ri or Ti plasmids |
| 6 | Bacteria | Any of the following:  (a) *Allorhizobium*species;  (b) *Corynebacterium glutamicum*;  (c) *Lactobacillus*species;  (d) *Lactococcus lactis*;  (e) *Oenococcus oeni*syn. *Leuconostoc oeni*;  (f) *Pediococcus* species;  (g) *Photobacterium angustum*;  (h) *Pseudoalteromonas tunicata*;  (i) *Rhizobium*species;  (j) *Sphingopyxis alaskensis*syn. *Sphingomonas alaskensis*;  (k) *Streptococcus thermophilus*;  (l) *Synechococcus* species strains PCC 7002, PCC 7942 and WH 8102;  (m) *Synechocystis*species strain PCC 6803;  (n) *Vibrio cholerae*CVD103‑HgR;  (o) *Zymomonas mobilis* | Non‑conjugative plasmids |
| 7 | Fungi | Any of the following:  (a) *Kluyveromyces lactis*;  (b) *Neurospora crassa*(laboratory strains);  (c) *Pichia pastoris*;  (d) *Saccharomyces cerevisiae*;  (e) *Schizosaccharomyces pombe*;  (f) *Trichoderma reesei*;  (g) *Yarrowia lipolytica* | All vectors |
| 8 | Slime moulds | Dictyostelium species | *Dictyostelium*shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2 |
| 9 | Tissue culture | Any of the following if they cannot spontaneously generate a whole animal:  (a) animal or human cell cultures (including packaging cell lines);  (b) isolated cells, isolated tissues or isolated organs, whether animal or human;  (c) early non‑human mammalian embryos cultured *in vitro* | plasmids;  replication defective viral vectors unable to transduce human cells;  polyhedrin minus forms of the baculovirus *Autographa californica* nuclear polyhedrosis virus (ACNPV) |
| 10 |  | Either of the following if they are not intended, and are not likely without human intervention, to vegetatively propagate, flower or regenerate into a whole plant:  (a) plant cell cultures;  (b) isolated plant tissues or organs | Disarmed Ri or Ti plasmids in *Agrobacterium radiobacter*, *Agrobacterium rhizogenes*(disarmed strains only) or *Agrobacterium tumefaciens*(disarmed strains only);  non‑pathogenic viral vectors |

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| A(iii) Description of the GMOs and dealings |
| **Description of work** Please consult the OGTR [Guidelines for the Transport, Storage and Disposal of GMOs](https://www.ogtr.gov.au/resources/publications/guidelines-transport-storage-and-disposal-gmos) for guidance.  For storage - consider whether GMOs may be sent for long term storage in a biobank at the completion of the experiments. |
| **How will the GMOs will be created or obtained (including import, if applicable)?**    **Describe the proposed experiments with the GMOs and any material derived from the GMOs:**  **How and where will GMOs, and material derived from GMOs, be stored?**    **How you propose to transport GMOs between approved facilities?**    **Describe the method of destruction and/or disposal of GMOs:**    **Will GMOs be exported overseas, or transported to another organization not listed in this application?** |

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| **Description of the GMO(s) –** *Use one row for each host/vector/nucleic acid combination* | | |
| **Scientific name of parent organism(s) being genetically modified** E.g. Escherichia coli K12 strain | **Method of genetic modification, including any vectors used** E.g. non-conjugative plasmid pUC19 transfer by electroporation | **Identity and function of nucleic acid & organism of origin**  Provide gene names, or gene family (e.g. cytokines) or gene function (e.g. ion transporters), and source organism E.g. Green fluorescent Protein (GFP) from Aequorea victoria |
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# Part B: Notifiable Low Risk Dealings (**NLRDs**)

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| B(i) Type of Notifiable Low Risk Dealing (NLRD) | | |
| **Notifiable low risk dealings suitable for at least physical containment level 1 (PC1)**  The following kinds of notifiable low risk dealings must be conducted in OGTR certified physical containment level 1 (PC1) facilities. | | |
| **Select all that apply** | **Item** | **Description of dealing** |
|  | 1.1(a) | a dealing involving a genetically modified laboratory guinea pig, a genetically modified laboratory mouse, a genetically modified laboratory rabbit or a genetically modified laboratory rat, unless:  (i) an advantage is conferred on the animal by the genetic modification; or  (ii) the animal is capable of secreting or producing an infectious agent as a result of the genetic modification; |
|  | 1.1(c) | a dealing involving a replication defective vector derived from *Human adenovirus* or *Adeno associated virus* in a host mentioned in item 9 of table A(ii) above, if the donor nucleic acid:  (i) cannot restore replication competence to the vector; and  (ii) does not confer an oncogenic modification or immunomodulatory effect in humans. |

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| **Notifiable low risk dealings suitable for at least physical containment level 2 (PC2)**  The following kinds of notifiable low risk dealings must be conducted in OGTR certified physical containment level 2 (PC2) facilities. | | |
| **Select all that apply** | **Item** | **Description of dealing** |
|  | 2.1(a) | a dealing involving whole animals (including non‑vertebrates) that:   1. involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism; and 2. does not involve any of the following:    1. a genetically modified laboratory guinea pig;    2. a genetically modified laboratory mouse;    3. a genetically modified laboratory rabbit;    4. a genetically modified laboratory rat;    5. a genetically modified *Caenorhabditis elegans*; |
|  | 2.1(aa) | a dealing involving a genetically modified laboratory guinea pig, a genetically modified laboratory mouse, a genetically modified laboratory rabbit, a genetically modified laboratory rat or a genetically modified *Caenorhabditis elegans*, if:   1. the genetic modification confers an advantage on the animal; and 2. the animal is not capable of secreting or producing an infectious agent as a result of the genetic modification; |
|  | 2.1(b) | a dealing involving a genetically modified plant |
|  | 2.1(c) | a dealing involving a host/vector system not mentioned in table A(ii), if neither host nor vector has been implicated in, or has a history of causing, disease in otherwise healthy:   1. human beings; or 2. animals; or 3. plants; or 4. fungi; |
|  | 2.1(d) | a dealing involving a host/vector system not mentioned in table A(ii), if:   1. the host or vector has been implicated in, or has a history of causing, disease in otherwise healthy: 2. human beings; or 3. animals; or 4. plants; or 5. fungi; and 6. the genetic modification is characterised; and 7. the characterisation of the genetic modification shows that it is unlikely to increase the capacity of the host or vector to cause harm;   *Example: A genetic modification would not comply with subparagraph (iii) if, in relation to the capacity of the host or vector to cause harm, it:*   1. *provides an advantage; or* 2. *adds a potential host species or mode of transmission; or* 3. *increases its virulence, pathogenicity or transmissibility.* |
|  | 2.1(e) | ***\*\*Note: also select either checkbox (i) or (ii) below\*\****  a dealing involving a host/vector system mentioned in table A(ii), if the donor nucleic acid:   1. **is characterised, and the characterisation shows that it may increase the capacity of the host or vector to cause harm; or** 2. **is uncharacterised nucleic acid from an organism that has been implicated in, or has a history of causing, disease in otherwise healthy:** 3. **human beings; or** 4. **animals; or** 5. **plants; or** 6. **fungi;** |
|  | 2.1(f) | a dealing involving a host/vector system mentioned in table A(ii) and producing more than 25 litres of GMO culture in each vessel containing the resultant culture, if:   1. the dealing is undertaken in a facility that is certified by the Regulator as a large-scale facility; and 2. the donor nucleic acid satisfies the conditions set out in item 4 subitem 2 of table A(i); |
|  | 2.1(g) | a dealing involving complementation of knocked out genes, if the complementation is unlikely to increase the capacity of the GMO to cause harm compared to the capacity of the parent organism before the genes were knocked out;  *Example: A dealing would not comply with paragraph (g) if it involved complementation that, in relation to the parent organism:*   1. *provides an advantage; or* 2. *adds a potential host species or mode of transmission; or* 3. *increases its virulence, pathogenicity or transmissibility.* |
|  | 2.1(h) | ***\*\*Note: also select either checkbox (i) or (ii) below\*\****  a dealing involving shotgun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in items 1 to 6 of table A(ii), if the donor nucleic acid is derived from either:   1. **a pathogen; or** 2. **a toxin producing organism;** |
|  | 2.1(i) | a dealing involving virions of a replication defective viral vector unable to transduce human cells and a host not mentioned in Part 2 of Schedule 2, if the donor nucleic acid cannot restore replication competence to the vector; |
|  | 2.1 (j) | a dealing involving virions of a replication defective nonretroviral vector able to transduce human cells, either without a host or with a host mentioned in table A(ii), if:   1. the donor nucleic acid cannot restore replication competence to the vector; and 2. the dealing is not a dealing mentioned in paragraph 1.1(c); |
|  | 2.1 (k) | a dealing involving virions of a replication defective nonretroviral vector able to transduce human cells and a host not mentioned in table A(ii), if:   * + 1. the donor nucleic acid cannot restore replication competence to the vector; and     2. the donor nucleic acid does not confer an oncogenic modification or immunomodulatory effect in humans; |
|  | 2.1 (l) | ***\*\*Note: also select either checkbox (A) or (B) below\*\****  a dealing involving virions of a replication defective retroviral vector able to transduce human cells, either without a host or with a host mentioned in table A(ii), if:   1. all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble new virions without these functions being supplied *in trans*; and 2. viral genes needed for virion production in the packaging cell line are expressed from independent, unlinked loci with minimal sequence overlap with the vector to limit or prevent recombination; and 3. either: 4. **the retroviral vector includes a deletion in the Long Terminal Repeat sequence of DNA that prevents transcription of genomic RNA following integration into the host cell DNA; or** 5. **the packaging cell line and packaging plasmids express only viral genes *gagpol*, *rev* and an envelope protein gene, or a subset of these;** |
|  | 2.1 (m) | ***\*\*Note: also select either checkbox (A) or (B) below\*\****  a dealing involving virions of a replication defective retroviral vector able to transduce human cells and a host not mentioned in table A(ii), if:   1. the donor nucleic acids does not confer an oncogenic modification or immunomodulatory effect in humans; and 2. all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble new virions without these functions being supplied *in trans*; and 3. viral genes needed for virion production in the packaging cell line are expressed from independent, unlinked loci with minimal sequence overlap with the vector to limit or prevent recombination; and 4. either: 5. **the retroviral vector includes a deletion in the Long Terminal Repeat sequence of DNA that prevents transcription of genomic RNA following integration into the host cell DNA; or** 6. **the packaging cell line and packaging plasmids express only viral genes *gagpol*, *rev* and an envelope protein gene, or a subset of these.** |

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| **Notifiable low risk dealings suitable for at least physical containment level 3 (PC3)**  The following kinds of notifiable low risk dealings must be conducted in OGTR certified physical containment level 3 facilities. | | |
| **Select all that apply** | **Item** | **Description of dealing** |
|  | 2.2 | A kind of dealing that   1. is a kind mentioned in Notifiable low risk dealings suitable for at least physical containment level 2; and 2. involves a micro-organism that satisfies the criteria in [**AS/NZS 2243.3:2022 for classification as Risk Group 3**](https://au.i2.saiglobal.com/management/display/index/0/54419/-/860cd61dc45e5f3e40e63c4990224026)   ***RISK GROUP 3 –*** *(high individual risk, limited community risk) – a microorganism, or material containing microorganisms, that* ***usually causes serious human, plant, insect or animal disease*** *and may present a serious risk to laboratory workers. It could present a risk if spread in the community, in a region, to the livestock industry or the environment, but there are usually effective preventive measures or treatment available.*  ***Examples of bacteria of risk group 3:*** *Bacillus anthracis; Bartonella bacilliformis; Burkholderia mallei; Brucella spp.; Chlamydia psittaci; Coxiella burnetii; Francisella tu/arensis (type A); Mycobacterium tuberculosis complex; Rickettsia spp.; Yersinia pestis*  ***Examples of fungi or fungi-like organisms of risk group 3:*** *Blastomyces dermatitidis; Coccidioides immitis; Coccidioides posadasii; Histoplasma spp.; Paracoccidioides brasiliensis; Penicillium marneffei*  ***Examples of viruses of risk group 3:*** *Lymphochoriomeningitis (LCM) neurotropic strains; Oropouche; Phlebovirus; Hantaan and related viruses; SARS coronavirus; Japanese encephalitis; St Louis encephalitis; Tick-borne viruses; West Nile; Yellow fever; Avian influenza; Influenza (highly pathogenic strains); Mapuera; Newcastle disease (exotic strains); Human Iymphotropic virus 1; Human lymphotropic virus 2; Human immunodeficiency virus; Australian bat lyssavirus; Rabies fixed strain (CVS II); Chikungunya Eastern equine encephalitis; Western equine encephalitis Venezuelan equine encephalitis.* |

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| B(ii) Description of the NLRD GMOs and dealings | |
| **Summary of the GMOs** Provide a brief summary of each NLRD GMO in this application and indicate the dealing type for each GMO. This information will be notified to the OGTR, but not published in the [GMO Record](https://www.ogtr.gov.au/gmo-dealings).  For example:  1) Mus musculus IL2 receptor gamma chain knockout (NLRD PC1 1.1(a))  2) Arabidopsis thaliana transformed with agrobacterium containing constructs for overexpression of ABC transporters (NLRD PC2 2.1(b))  3) Rattus norvegicus cell lines transduced with lentivirus containing the human hCG gene (NLRD PC2 2.1(L iii A). | |
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| **Description of the dealings to be conducted with the GMOs** | |
| Please **‘un-check’** from the list of dealings any that you specifically know will **definitely not** be undertaken.  ***NOTE:*** *A dealing includes the possession, supply or use of the GMO, for the purposes of, or in the course of, a dealing mentioned in any of paragraphs listed.* | Conduct experiments with the GMO |
| Make, develop, produce or manufacture the GMO |
| Breed the GMO |
| Propagate the GMO |
| Use the GMO in the course of manufacture of a thing\* that is not the GMO (\**As defined in the Gene technology Act 2000, a* ***thing****includes a substance, and a thing in electronic or magnetic form).*  If yes, complete following details Is the thing\* subject to regulation by other agencies (e.g., Food Standards Australia, Australian Pesticides and Veterinary Medicines Association, Therapeutic Goods Administration)?  Yes Ø Agency        No |
| Grow, raise or culture the GMO |
| Import the GMO  If yes, complete following details Is the import subject to AQIS approval?  Yes Ø Import Permit ID        No |
| Transport the GMO |
| Dispose of the GMO |
| Store the GMO |
| **Description of work** Describe the following for each of the kinds of notifiable low risk dealings. If there are different kinds of dealings proposed, e.g. PC1 GM mice and PC2 GM microorganisms, make sure you answer the question for each type. For storage - consider whether GMOs may be sent for long term storage in a biobank. Please consult the OGTR [Guidelines for the Transport, Storage and Disposal of GMOs](https://www.ogtr.gov.au/resources/publications/guidelines-transport-storage-and-disposal-gmos) for guidance. | |
| **How will the GMOs will be created or obtained (including import, if applicable)?**    **Describe the proposed experiments with the GMOs and any material derived from the GMOs:**  **How and where will GMOs, and material derived from GMOs, be stored?**    **Will GMOs be stored outside of an OGTR certified facility?**    **How you propose to transport GMOs between approved facilities?**    **Describe the method of destruction and/or disposal of GMOs:**    **Will GMOs be exported overseas, or transported to another organization not listed in this application?** | |

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| **Description of the GMO(s) –** *Use one row for each host/vector/nucleic acid combination* | | | |
| **Scientific name of parent organism(s)** The parent organism means the organism that you propose to genetically modify. It also includes intended host cells, e.g. tissue culture cells or host animal cells transduced by a vector. | **Method of genetic modification, including any vectors used** Describe the method of modification – e.g. knock-out, crossing of GM animals, CRISPR/Cas9 gene editing, prime editing. For dealings involving viral vectors please provide details of each of the plasmids to be used. | | **Identity and function of nucleic acid & organism of origin**  Provide gene names, or gene family (e.g. cytokines) or gene function (e.g. ion transporters), and source organism |
| E.g. Mus musculus | E.g. microinjection of CRISPR/Cas9 construct into embryo | | E.g. Cas9 from Streptococcus pyogenes  Green fluorescent Protein (GFP) from Aequorea victoria |
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|  |  | |  |
| **Modified trait(s) and gene(s) responsible** | | | |
| **Class of modified trait (select all that apply)** | | **Names of gene(s) responsible** | |
| Abiotic stress resistance | |  | |
| Altered agronomic characteristics | |  | |
| Altered biocontrol characteristics | |  | |
| Altered bioremediation characteristics | |  | |
| Altered biosensor characteristics | |  | |
| Altered horticultural characteristics | |  | |
| Altered nutritional characteristics | |  | |
| Altered pharmaceutical characteristics | |  | |
| Altered physical product characteristics | |  | |
| Altered physiological characteristics | |  | |
| Antibiotic resistance | |  | |
| Antigen expression | |  | |
| Attenuation | |  | |
| Bacterial resistance | |  | |
| Disease resistance | |  | |
| Fungal resistance | |  | |
| Growth factor expression | |  | |
| Herbicide tolerance | |  | |
| Immuno-modulatory protein expression | |  | |
| Pest resistance | |  | |
| Pesticide resistance | |  | |
| Protein expression | |  | |
| Reporter/marker gene expression | |  | |
| Virus resistance | |  | |
| Other | |  | |

# Part C: Dealings that are **not** notifiable low risk dealings

If a dealing is not a notifiable low risk dealing, or an exempt dealing, as provided by these Regulations, a person undertaking the dealing must be **authorised by a GMO licence** unless the dealing is within one of the other exceptions to licensing provided by the Act: [see section 32 of the Act.](https://www.legislation.gov.au/Details/C2016C00792)

|  |  |  |
| --- | --- | --- |
| C(i) Type of licenced contained dealing | | |
| **These dealings require a licence from the Gene Technology Regulator** | | |
| **Select all that apply** | **Item** | **Description of dealing** |
|  | 3.1(a) | a dealing (other than a dealing mentioned in paragraph 2.1 (h)) involving cloning of nucleic acid encoding a toxin having an LD50 of less than 100 micrograms per kilogram; |
|  | 3.1(b) | a dealing involving high level expression of toxin genes, even if the LD50 is 100 micrograms per kilogram or more; |
|  | 3.1(c) | a dealing (other than a dealing mentioned in paragraph 2.1 (h)) involving cloning of uncharacterised nucleic acid from a toxin‑producing organism; |
|  | 3.1(d) | a dealing involving virions of a replication defective viral vector and a host not mentioned in Part 2 of Schedule 2, if:  (i) the donor nucleic acid confers an oncogenic modification or immunomodulatory effect in humans; and  (ii) the dealing is not a dealing mentioned in paragraph 2.1(i); |
|  | 3.1(e) | a dealing involving a replication competent virus or viral vector, other than a vector mentioned in Part 2 of Schedule 2, if the genetic modification confers an oncogenic modification or immunomodulatory effect in humans; |
|  | 3.1(f) | a dealing involving, as host or vector, a micro‑organism, if:  (i) the micro‑organism has been implicated in, or has a history of causing, disease in otherwise healthy:  (A) human beings; or  (B) animals; or  (C) plants; or  (D) fungi; and  (ii) none of the following sub‑subparagraphs apply:  (A) the host/vector system is a system mentioned in Part 2 of Schedule 2;  (B) the genetic modification is characterised and its characterisation shows that it is unlikely to increase the capacity of the host or vector to cause harm;  (C) the dealing is a dealing mentioned in paragraph 2.1 (g);  Example: A genetic modification would not comply with sub‑subparagraph (B) if, in relation to the capacity of the host or vector to cause harm, it:  (a) provides an advantage; or  (b) adds a potential host species or mode of transmission; or  (c) increases its virulence, pathogenicity or transmissibility. |
|  | 3.1(g) | a dealing involving the introduction, into a micro‑organism,of nucleic acid encoding a pathogenic determinant,unless:  (i) the dealing is a dealing mentioned in paragraph 2.1 (g); or  (ii) the micro‑organism is a host mentioned in Part 2 of Schedule 2; |
|  | 3.1(h) | a dealing involving the introduction into a micro‑organism, other than a host mentioned in Part 2 of Schedule 2, of genes whose expressed products are likely to increase the capacity of the micro‑organisms to induce an autoimmune response; |
|  | 3.1(i) | a dealing involving use of a viral or viroid genome, or fragments of a viral or viroid genome, to produce a novel replication competent virus with an increased capacity to cause harm compared to the capacity of the parent or donor organism;  *Example: A dealing would comply with paragraph (i) if it produces a novel replication competent virus that has a higher capacity to cause harm to any potential host species than the parent organism because the new virus has:*  *(a) an advantage; or*  *(b) a new potential host species or mode of transmissibility; or*  *(c) increased virulence, pathogenicity or transmissibility.* |
|  | 3.1(j) | a dealing, other than a dealing mentioned in paragraph 2.1 (l) or (m), with a replication defective retroviral vector (including a lentiviral vector) able to transduce human cells; |
|  | 3.1(k) | a dealing involving a genetically modified animal, plant or fungus that is capable of secreting or producing infectious agents as a result of the genetic modification; |
|  | 3.1(l) | a dealing producing, in each vessel containing the resultant GMO culture, more than 25 litres of that culture, other than a dealing mentioned in paragraph 2.1 (f); |
|  | 3.1(m) | a dealing that is inconsistent with a policy principle issued by the Ministerial Council; |
|  | 3.1(n) | a dealing involving the intentional introduction of a GMO into a human being, unless the GMO:   * 1. is a human somatic cell; and   2. cannot secrete or produce infectious agents as a result of the genetic modification; and   3. if it was generated using viral vectors:  1. has been tested for the presence of viruses likely to recombine with the genetically modified nucleic acid in the somatic cells; and 2. the testing did not detect a virus mentioned in sub‑subparagraph (A); and 3. the viral vector used to generate the GMO as part of a previous dealing is no longer present in the somatic cells; |
|  | 3.1(o) | a dealing involving a genetically modified pathogenic organism, if the practical treatment of any disease or abnormality caused by the organism would be impaired by the genetic modification; |
|  | 3.1(p) | JCU does not have facilities to conduct work with risk group 4. a dealing involving a microorganism that satisfies the **criteria in** **[AS/NZS 2243.3:2022 for classification as Risk Group 4](https://au.i2.saiglobal.com/management/display/index/0/54419/-/860cd61dc45e5f3e40e63c4990224026)**  ***RISK GROUP 4*** *(high individual and community risk) - a microorganism that usually produces* ***life-threatening human or animal disease****, represents a significant risk to laboratory workers and* ***may be readily transmissible from one individual to another****. Effective* ***treatment and preventative measures are not usually available*.**  ***Examples of viruses of risk group 4:*** *Guanarito arenavirus; Mopeia viruses; Ebola; Tick-born encephalitis; Junin arenavirus; Sabia virus; Marburg; Herpes virus simiae (B virus); Lassa arenavirus; Crimean-Congo haemorrhagic fever; Kyasanur Forest Disease; Hendra paramyxovirus; Machupo arenavirus; Hazara nairovirus; Omsk haemorrhagic fever disease; Nipah paramyxovirus* |
|  | 3.1(q) | a dealing involving a micro‑organism that [satisfies the criteria in AS/NZS 2243.3:2022 for classification as Risk Group 3](https://au.i2.saiglobal.com/management/display/index/0/54419/-/860cd61dc45e5f3e40e63c4990224026) and that is not undertaken:   1. in a facility that is certified by the Regulator to at least physical containment level 3 and that is appropriate for the dealing; or 2. in a facility that the Regulator has agreed in writing is a facility in which the dealing may be undertaken; |
|  | 3.1(r) | a dealing involving a GMO capable of sexual reproduction, the sexual progeny of which are, as a result of the genetic modification, more likely to inherit a particular nucleotide sequence or set of nucleotide sequences (when compared to inheritance from the unmodified parent organism); |
|  | 3.1(s) | a dealing involving a viral vector that can modify an organism capable of sexual reproduction, so that the sexual progeny of the organism are more likely to inherit a particular nucleotide sequence or set of nucleotide sequences (when compared to inheritance from the unmodified parent organism). |

**Note:** *A modification that increases the likelihood of inheritance of a nucleotide sequence or sequences, as described in paragraphs 3.1(r) and 3.1(s), is generally known as an engineered* ***gene drive.***

|  |  |  |
| --- | --- | --- |
| **C(ii) Description of the GMO(s) –** *Use one row for each host/vector/nucleic acid combination* | | |
| **Scientific name of parent organism(s)** The parent organism means the organism that you propose to genetically modify. It also includes intended host cells, e.g. tissue culture cells or host animal cells transduced by a vector. | **Method of genetic modification, including any vectors used** Describe the method of modification – e.g. knock-out, crossing of GM animals, CRISPR/Cas9 gene editing, prime editing. For dealings involving viral vectors please provide details of each of the plasmids to be used. | **Identity and function of nucleic acid & organism of origin**  Provide gene names, or gene family (e.g. cytokines) or gene function (e.g. ion transporters), and source organism |
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| ***Replication defective non-*retroviral *vectors*** [(Refer to Gene Technology Regulations)](https://www.legislation.gov.au/Details/F2020C00957) for relevant parts and sections outlined in table. | | | |
| --- | --- | --- | --- |
| **Viral vector type** | **Characteristics of donor nucleic acid, donor organism or modification** | ***In vitro1*** | ***In vivo*** |
| Any | toxin or uncharacterised gene from toxin producing organism | DNIR, [S3 p3.1 (a), (b) or (c)](https://www.legislation.gov.au/Details/F2020C00957) | |
| genes whose expressed products are likely to increase the capacity of the viral vector to induce an autoimmune response | DNIR, [S3 p3.1 (h)](https://www.legislation.gov.au/Details/F2020C00957) | |
| creates novel replication competent virus with increased capacity to cause harm (e.g: new potential host species or mode of transmission; or increased virulence or transmissibility) | DNIR, [S3 p3.1 (i)](https://www.legislation.gov.au/Details/F2020C00957) | |
| can modify an organism so as to increase the likelihood of inheritance of particular nucleotide sequence(s) (i.e. create an engineered gene drive) | DNIR, [S3 p3.1 (s)](https://www.legislation.gov.au/Details/F2020C00957) | |
| Risk Group 4 virus2 | any | DNIR, [S3 p3.1 (p)](https://www.legislation.gov.au/Details/F2020C00957) | |
| Risk Group 3 virus2 | any | DNIR, [S3 p3.1 (q)](https://www.legislation.gov.au/Details/F2020C00957) if not in an appropriate PC3 facility | |
| Unable to transduce human cells (and not Risk Group 3 2) | unlikely to increase capacity to cause harm; cultures used are ≤ 25 L | Exempt, [S2 p1 item 4](https://www.legislation.gov.au/Details/F2020C00957) | NLRD, [S3 p2.1 (i)](https://www.legislation.gov.au/Details/F2020C00957) |
| unlikely to increase capacity to cause harm; cultures used are > 25 L | NLRD, [S3 p2.1 (f)](https://www.legislation.gov.au/Details/F2020C00957) | N/A |
| may increase capacity to cause harm; uncharacterised nucleic acid from a pathogen | NLRD, [S3 p2.1 (e)](https://www.legislation.gov.au/Details/F2020C00957) | NLRD, [S3 p2.1 (i)](https://www.legislation.gov.au/Details/F2020C00957) |
| Able to transduce human cells: *Human adenovirus* or *Adeno associated virus* | does not confer an oncogenic modification or immunomodulatory effect in humans; not a toxin | NLRD, [S3 p1.1 (c)](https://www.legislation.gov.au/Details/F2020C00957) | NLRD, [S3 p2.1 (k)](https://www.legislation.gov.au/Details/F2020C00957) |
| confers an oncogenic modification or immunomodulatory effect in humans; not a toxin | NLRD, [S3 p2.1 (j)](https://www.legislation.gov.au/Details/F2020C00957) | DNIR, [S3 p3.1 (d)](https://www.legislation.gov.au/Details/F2020C00957) |
| would impair practical treatment of any disease or abnormality caused by the virus (e.g. drug resistance) | DNIR, [S3 p3.1 (o)](https://www.legislation.gov.au/Details/F2020C00957) | |
| Able to transduce human cells: all other viruses | not a toxin | NLRD, [S3 p2.1 (j)](https://www.legislation.gov.au/Details/F2020C00957) | NLRD, [S3 p2.1 (k)](https://www.legislation.gov.au/Details/F2020C00957) |
| oncogenic modification or immunomodulatory in humans | NLRD, [S3 p2.1 (j)](https://www.legislation.gov.au/Details/F2020C00957) | DNIR, [S3 p3.1 (d)](https://www.legislation.gov.au/Details/F2020C00957) |
| would impair the practical treatment of any disease or abnormality caused by the virus (e.g. drug resistance) | DNIR, [S3 p3.1 (o)](https://www.legislation.gov.au/Details/F2020C00957) | |

## Appendix 1: Guidance on the classification of contained dealings with viral vectors [(Refer to Gene Technology Regulations)](https://www.legislation.gov.au/Details/F2020C00957)

DNIR = dealing not involving intentional release, exempt = exempt dealing, NLRD = notifiable low risk dealing; [p = Part (of the Regulations); S = Schedule (of the Regulations)](https://www.legislation.gov.au/Details/F2020C00957)

1 In cell or tissue culture, as packaged virions without a host, or naked vector nucleic acid (if the nucleic acid can produce infectious particles when introduced into a suitable host cell). 2 Unmodified parent virus satisfies the criteria in [AS/NZS 2243.3:2022 for classification in the indicated Risk Group](https://au.i2.saiglobal.com/management/display/index/0/54419/-/860cd61dc45e5f3e40e63c4990224026). 3 As well as including one of the indicated safety features to reduce the likelihood of recombination leading to replication competence being

regained, additional requirements apply, including that all viral genes must be removed from the vector and only *gagpol*, *env* *rev* viral sequences may be present in the packaging system.

| *Replication defective* retroviral *vectors* [(Refer to Gene Technology Regulations)](https://www.legislation.gov.au/Details/F2020C00957) for relevant parts and sections outlined in table. | | | |
| --- | --- | --- | --- |
| **Viral vector type** | **Characteristics of donor nucleic acid, donor organism or modification** | ***In vitro1*** | ***In vivo*** |
| Any | toxin or uncharacterised gene from toxin producing organism | DNIR, S3 p3.1 (a), (b) or (c) | |
| genes whose expressed products are likely to increase the capacity of the virus/viral vector to induce an autoimmune response | DNIR, S3 p3.1 (h) | |
| creates novel replication competent virus with increased capacity to cause harm (e.g: new potential host species or mode of transmission; or increased virulence or transmissibility) | DNIR, S3 p3.1 (i) | |
| would impair practical treatment of any disease or abnormality caused by the viral vector (e.g. drug resistance) | DNIR, S3 p3.1 (o) | |
| can modify an organism so as to increase the likelihood of inheritance of particular nucleotide sequence(s) (i.e. create an engineered gene drive) | DNIR, S3 p3.1 (s) | |
| Unable to transduce human cells | unlikely to increase capacity to cause harm; cultures used are ≤ 25 L | Exempt, S2 p1 item 4 | NLRD, S3 p2.1 (i) |
| unlikely to increase capacity to cause harm; cultures used are > 25 L | NLRD, S3 p2.1 (f) | N/A |
| may increase capacity to cause harm (e.g. pathogenic determinant); not a toxin | NLRD, S3 2.1 (e) | NLRD, S3 p2.1 (i) |
| Able to transduce human cells3:  Self inactivating **and/or** accessory genes  **not** present | does not confer an oncogenic modification or immunomodulatory effect in humans; not a toxin | NLRD, S3 p2.1 (l) | NLRD, S3 p2.1 (m) |
| confers an oncogenic modification or immunomodulatory effect in humans; not a toxin | NLRD, S3 p2.1 (l) | DNIR, S3 p3.1 (d) & (j) |
| Able to transduce human cells:  not self inactivating  **and**  accessory genes  **are** present | does not confer an oncogenic modification and not immunomodulatory effect in humans; not a toxin | DNIR, S3 p3.1 (j) | |
| oncogenic modification or immunomodulatory in humans | DNIR, S3 p3.1 (d) & (j) | |
| Risk Group 4 virus2 | any | DNIR, S3 p3.1 (p) | |

| ***Replication competent vectors*** [(Refer to Gene Technology Regulations)](https://www.legislation.gov.au/Details/F2020C00957) for relevant parts and sections outlined in table. | | | |
| --- | --- | --- | --- |
| **Viral vector type** | **Characteristics of donor nucleic acid or donor organism** | ***In vitro1*** | ***In vivo*** |
| Any | can modify an organism so as to increase the likelihood of inheritance of particular nucleotide sequence(s) (i.e. create an engineered gene drive) | DNIR, S3 p3.1 (s) | |
| Non-pathogenic plant viral vector  or  Baculovirus (polyhedrin minus forms of *Autographa californica nuclear polyhedrosis virus*) | unlikely to increase capacity to cause harm; cultures used are ≤ 25 L | Exempt, S2 p1 item 4 | NLRD, S3 p2.1 (c) |
| unlikely to increase capacity to cause harm; cultures used are > 25 L | NLRD, S3 p2.1 (f) | N/A |
| may increase capacity to cause harm | NLRD, S3 p2.1 (e) | DNIR, S3 p3.1 (f) & (g) |
| toxin or uncharacterised gene from toxin producing organism | DNIR, S3 p3.1 (a), (b) or (c) | |
| genes whose expressed products are likely to increase the capacity of the virus/viral vector to induce an autoimmune response | DNIR, S3 p3.1 (h) | |
| creates novel replication competent virus with increased capacity to cause harm (e.g: new potential host species or mode of transmission; or increased virulence or transmissibility) | DNIR, S3 p3.1 (i) | |
| Risk Group 4 virus2 | any | DNIR, S3 p3.1 (p) | |
| Risk Group 3 virus2 | any | DNIR, S3 p3.1 (q) if not in an appropriate PC3 facility | |
| All other replication competent viruses | not a pathogenic determinant and not a toxin and not an oncogenic modification and not immunomodulatory in humans | NLRD, S3 p2.1 (c) or (d) | |
| toxin or an uncharacterised gene from toxin producing organism | DNIR, S3 p3.1 (a), (b) or (c) | |
| confers an oncogenic modification or immunomodulatory effect in humans | DNIR, S3 p3.1 (e) | |
| pathogenic determinant or may otherwise increase capacity of virus to cause harm | DNIR, S3 p3.1 (f) or (g) | |
| genes whose expressed products are likely to increase the capacity of the virus/viral vector to induce an autoimmune response | DNIR, S3 p3.1 (h) | |
| creates novel replication competent virus with increased capacity to cause harm (e.g: new potential host species or mode of transmission; or increased virulence or transmissibility) | DNIR, S3 p3.1 (i) | |
| would impair practical treatment of any disease or abnormality caused by the virus (e.g. drug resistance) | DNIR, S3 p3.1 (o) | |

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## Appendix 2: Overview – status of organisms modified using gene editing and other new technologies [(Refer to Gene Technology Regulations)](https://www.legislation.gov.au/Details/F2020C00957)

**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 (nonhomologous end joining) means that no nucleic acid template was added to cells to guide genome repair following SDN application. This spontaneous repair of the genome can lead to a mutation causing gene silencing, gene knock-out or a change in the activity of a gene. 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.

**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)](https://www.legislation.gov.au/Details/F2020C00957) | **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))](https://www.legislation.gov.au/Details/F2020C00957) | **Not a GMO**  [(Schedule 1 item 9(b))](https://www.legislation.gov.au/Details/F2020C00957) | **GMO** if SDN transgene also inherited  **Not a GMO** if no SDN transgene inherited (Schedule 1 item 9(b)) |

Some examples illustrating the status of organisms produced while 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.

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 oligonucleotide‐directed mutagenesis (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**).](https://www.legislation.gov.au/Details/F2020C00957)

**SDN-2** genome editing involves a template-guided repair (homology-directed repair) of a targeted double-strand break using a sequence donor, typically short single-stranded DNA (short template with one or several nucleotide difference). The donor is recognised as a repair template, allowing the introduction of the mutation(s) at the target site(s).

**SDN-3** genome editing Involves a template-guided repair (homology-directed repair) of a targeted double-strand break using a sequence donor, typically double-stranded DNA containing an entire gene or an even longer genetic element(s). The donor is recognised as a repair template, allowing the introduction of the gene or genetic element(s) at the target site.

In each case, the method used to modify the organism is central to determining whether 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**](https://www.legislation.gov.au/Details/F2020C00957). 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 be translated into a protein or 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 or transiently 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.

## Organisms derived from GMOs but with NO traits from gene technology

Consistent with the definition of a GMO in the Act, and for the avoidance of doubt, 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**)](https://www.legislation.gov.au/Details/F2020C00957)
* 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**).](https://www.legislation.gov.au/Details/F2020C00957)

Modifications produced using SDN techniques are traits that occurred because of gene technology, so [**Schedule 1 item 8**](https://www.legislation.gov.au/Details/F2020C00957) does not exclude these organisms from being GMOs. However, other items described above do exclude SDN-1 organisms from this regulation.

## Appendix 3: Containment requirements and facility certification

## Containment requirements and facility certification

Some GMO dealings must not involve intentional release of GMOs into the environment. Generally, this means that they are undertaken in physical containment (PC) facilities. The Regulator may need to [certify the facilities](https://www.ogtr.gov.au/apply-gmo-approval/apply-physical-containment-facility-certification).

This table shows the containment requirements for each type of dealing.

| **Category** | **Containment requirements** |
| --- | --- |
| Exempt | Yes No intentional release to the environment |
| NLRD | Yes PC1 or PC2 (usually) |
| DNIR | Yes ≥ PC2 (usually) or appropriate clinical facilities, and other conditions will apply |
| DIR (limited and controlled release) | Generally no containment measures, but confinement measures will be required based on size/scope of release sought by applicant; and other licence conditions will apply |
| DIR (except for limited and controlled release) | Generally no containment measures, but confinement measures may be required, determined on a case-by-case basis, and other licence conditions will apply |
| Inadvertent dealing | Containment and/or disposal measures will apply |
| GMO Register | Containment measures may be required |
| EDD | Containment and/or disposal measures may be included in EDD conditions |

## References

1. Friedrichs S, et al. An overview of regulatory approaches to genome editing in agriculture. Biotechnology Research and Innovation. 2019;3(2):208-20.