Biosafety - Dealings Involving Genetically Modified Organisms Procedure

Section 1 - Summary

(1) The purpose of this Procedure is to protect the health and safety of people, animals and the environment, by identifying risks posed by, or as a result of, dealings with Genetically Modified Organisms (GMOs) at Victoria University (VU).

(2) At all times, dealings with GMOs must be conducted in accordance with the Gene Technology Act 2000 and associated regulations. Dealings must also comply with the University's health and safety systems including the Safe Work Practices and Biological Work Requirements. These processes ensure compliance with other State and Federal Acts and Regulations, as well as Codes of Practice, and Australian Standards.

Section 2 - Scope

(3) This Procedure applies to all work areas of the University where GMOs are used, stored, handled, transported and disposed of. It applies to all personnel unertaking or supervising work with GMOs, as well as those working in an Office for Gene Technology Regulator (OGTR) certified containment facilities, including any external persons accessing University facilities.

(4) All VU personnel and external persons accessing University facilities must ensure their work is compliant with the relevant regulations, codes and standards at all times.

Section 3 - Policy/Regulation

(5) Biosafety Policy

Section 4 - Procedures

Part A - Summary of Roles and Responsibilities

Roles	Responsibilities
Vice-Chancellor (VC)	Is the University's OGTR Licensee and as such has ultimate responsibility for the maintenance of the University's status as an accredited organisation under the Gene Technology legislation.
Deputy Vice-Chancellor, Research & Impact (DVC-RI)	Responsible to the VC for VU's Institutional Biosafety Committee (IBC) and its implementation of requirements as specified by the OGTR and associated Acts, regulations and legislation. The named primary contact and licensee delegate on the VU OGTR License.

Roles	Responsibilities
Executive Director, Research Services	Responsible to the DVCRI to ensure that the Senior Manager, Research Infrastructure & Biosafety, advises and reports on the regulatory and legislative requirements of GMO dealings, and are adequately supported to develop, implement, monitor and review associated procedures and guidelines.
Senior Manager, Research Infrastructure & Biosafety	Authorised to advise on and report to the IBC on regulatory and legislative requirements of GMO dealings, and to develop, implement, monitor and review associated procedures and guidelines.
Directors, Executive Deans and Heads of Department	Ensure that all staff and students receive appropriate information and training necessary for them to become a competent person and conduct GMO dealings accordance with all regulatory and legislative requirements.
Manager, Technical Services	Ensure that designated research spaces are adequately supported so that GMO dealings can be conducted in a compliant and safe manner. Ensure that Technical Managers have resources to develop and implement training and procedures necessary to ensure that all GMO dealings are conducted in accordance with regulatory and legislative requirements.
Technical Managers and Manager, Animal Facility	Ensure that all end-users of OGTR certified facilities are adequately trained as competent persons, and that there are procedures in place to ensure that all GMO dealings are conducted in accordance with regulatory and legislative requirements.
Primary/Chief Investigators (including Academic Supervisors, Research Supervisors and Unit Conveners)	Responsible for the health and safety of the undergraduate and postgraduate students they supervise, in addition to volunteers and staff employed under them. Ensure that students and staff are aware of and abide by VU's procedures for GMO dealings.
Staff, Students, Volunteers and External Users of University Facilities	Ensure that they follow safety guidelines and abide by the procedures for GMO dealings set out by VU and their relevant facility manager and Project/Supervisor/Primary Investigator. Ensure that their actions do not put themselves, or any other individual at risk.
Senior Officer, Animal Ethics & Biosafety	Act as the IBC Secretary and as such are responsible for receiving and sending communications between Primary/Chief Investigators, end-users, facility managers and the IBC.

Part B - General Requirements

Accreditation

(6) The University must comply with all conditions described in the OGTR Guidelines for the Accreditation of Organisations, in order to maintain its OGTR accreditation.

(7) The Vice-Chancellor is the University's Licensee and as such has ultimate responsibility for the maintenance of the University's status as an accredited organisation under the gene technology legislation. The Vice-Chancellor has delegated the task of managing compliance in laboratories and high-risk project approval to the Deputy Vice-Chancellor, Research & Impact, who is the named primary contact and licensee delegate on the VU OGTR License. They are responsible for the development, compliance monitoring and review of this Procedure and any associated guidelines.

(8) The Senior Manager, Research Infrastructure & Biosafety is responsible for the implementation of this Procedure.

(9) The Institutional Biosafety Committee (IBC), and the persons listed as the contact between the OGTR and the University (Deputy Vice-Chancellor, Research & Impact, and Senior Manager, Research Infrastructure & Biosafety), provide assistance in meeting the compliance requirements.

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Institutional Biosafety Committee (IBC)

(10) The University must establish an IBC. The membership and collective technical expertise of the IBC must meet the University's needs and must include an independent member.

(11) The Committee must be supported, resourced and appropriately indemnified. The operation of IBC must be in accordance with its documented VU IBC Terms of Reference.

Reporting to the Office of the Gene Technology Regulator (OGTR)

(12) As an Accredited Organisation, the University must submit an Annual Report to the Gene Technology Regulator.

Part C - Gene Technology Training and Competency

(13) The University's training program structure is detailed in the Biosafety - Dealings Involving Risk Group Agents Procedure.

(14) The University will provide gene technology information and training regarding OGTR behavioural requirements, for staff and postgraduate students (including Honours students) and for staff from affiliated organisations, such that they can be deemed competent persons.

(15) Technical Managers and/or the Manager, Animal Facility must ensure that technical personnel are competent before they commence working in an OGTR certified containment facility.

(16) Technical Managers and/or the Manager, Animal Facility must ensure that access to a facility is confined to persons who are trained in a specific set of behaviours appropriate to the facility itself and to the dealings being conducted in that facility. The Institutes/Colleges (and Technical Services personnel maintaining the facilities on their behalf) must ensure that all persons working in a certified facility are instructed in any specific OGTR-imposed conditions of certification and any variations on that certification.

(17) The IBC may request evidence of the competency of any facility users at any time.

(18) Academic and Professional Staff supervising end-users utilising OGTR certified facilities and/or undertaking GMO dealings, or listed as Primary/Chief Investigators on IBC-approved projects, must:

a. ensure that staff and students are inducted into the facility, including any specific behavioural requirement appropriate to the facility;
b. inform staff and students of the specific licence conditions, and any specific facility-certification conditions;
c. ensure that all staff and students who are working with a Dealing Not Involving Release (DNIR) have signed a training and information statement related to the specific information contained in the DNIR approval;
d. ensure that all work is covered by a documented procedure;
e. ensure that staff and students are competent before they undertake any GMO dealing;
f. retain IBC assessment records for eight years from the date of assessment;
g. retain evidence of training;
h. provide ongoing information and appropriate supervision;
i. provide appropriate training and supervision for undergraduate and short term students.

Part D - OGTR Certified Physical Containment Facilities

Determine Facility Certification Requirements

(19) Exempt dealings are not required to be carried out in an OGTR certified facility. All other GMO dealings require

that the facility is certified with the OGTR.

(20) The level of containment (PC1- 4) for GMO dealings will be determined by the risk group of the dealing.

Oversight of Facilities

(21) The University must ensure that all facilities in which GMO dealings are conducted have a designated Facility Manager or Laboratory Technician.

(22) The Institutes/Colleges must ensure that the type of OGTR certification for the facility remains appropriate to the risk associated with the GMOs with in the facility.

Facility Safety Manual & Standard Operating Procedures

(23) Technical Managers and the Manager, Animal Facility must ensure that the facility has current, documented procedures in place, preferably in the form of a safety manual.

(24) The safety manual should include:

a. all general and specific conditions of certification relevant to the physical containment level and type, as detailed in the relevant OGTR Guidelines for Certification of Physical Containment Facilities;
b. the specific work practices for the facility;
c. documented risk assessments, the identified controls;
d. laboratory maintenance requirements and records;
e. standard operating procedures;
f. training and supervision requirements for staff.

OGTR-Certification of Facilities

(25) Based on an assessment of current and proposed GMO dealings, the Senior Manager, Research Infrastructure & Biosafety, together with the Technical Managers and/or the Manager, Animal Facility must determine whether a facility is required to be certified by the OGTR, and to what containment level.

(26) The level of containment (OGTR PC1-4) for GMO dealings will be determined by the risk group of the dealing, as described in OGTR Guidelines.

(27) If certification is required, the facility owner must apply to the IBC via the Senior Manager, Research Infrastructure & Biosafety and arrange for the facility to be inspected against the relevant OGTR inspection checklist to document that the facility meets the required conditions for certification.

(28) The completed checklist and a detailed floor plan must be submitted to the IBC who will review the documentation and arrange for it to be signed by the Vice-Chancellor or delegate. The completed documentation is then submitted to the OGTR by the Senior Manager, Research Infrastructure & Biosafety, or delegate.

(29) Approval by the OGTR can take 90 working days from the date of receipt of the application. Until written approval is received, there must be no dealings involving GMOs in that facility.

Inspection of OGTR-Certified Facilities

(30) Physical containment facilities must be inspected prior to OGTR-certification. Inspection will be arranged by the IBC and will include an IBC authorised inspector.

(31) All OGTR-certified facilities must be inspected annually. These inspections are arranged by the IBC, who will then provide an inspection report to the Technical Manager and/or Manager, Animal Facility. The report must be made

available to the University or to the OGTR upon request.

(32) Independent of the annual inspection, the Senior Manager, Research Infrastructure & Biosafety and IBC may randomly inspect a facility at any time.

(33) The legislation allows the OGTR to undertake scheduled or unannounced inspections of all certified facilities.

Corrective Action Following Inspection

(34) For new certification requests, corrective actions must be completed before the OGTR will issue a certificate.

(35) Where an inspection report identifies any non-compliance with the OGTR conditions of certification, the Technical Manager and/or the Manager, Animal Facility must provide written confirmation to the IBC within a reasonable timeframe, that corrective actions have been completed. Failure to comply may result in a delay in receiving a new certification from the OGTR, or the suspension (or cancellation) of an existing certification by the OGTR.

Working in an OGTR-Certified Facility

(36) Where GMO dealings are required to be conducted in a certified facility, Technical Managers and/or the Manager, Animal Facility must ensure that these dealings are not undertaken until the certification documents are received from the OGTR and the necessary signage is displayed.

(37) All OGTR requirements for a certified facility must be complied with at all times by all personnel. This includes when non-GMO work is being performed in the facility.

Variation to a Facility OGTR Certification

(38) Changes to the agents used, the work undertaken or the space utilised within a certified facility may necessitate adjustments to ensure the acility meets containment requirements and safeguards both personnel and the environment. A Risk Assessment (according to the Risk Management Procedure) must be performed by the work group and submitted to the IBC for consideration.

(39) All requests to vary a certificate must be signed off by the University before being presented to the OGTR.

(40) Any proposal to vary, suspend or surrender a current OGTR facility certification must be submitted by the facility manager (or equivalent) to the IBC via the Senior Manager, Research Infrastructure & Biosafety (or delegate), who will liaise with the OGTR on behalf of the IBC. The variation must not be implemented without the written approval from the OGTR.

(41) The OGTR will issue new certification signage, which must replace the previous signage. Where a facility has had the certification surrendered or suspended, all OGTR certification signage must be removed.

Decommissioning/Surrendering Physical Containment Facilities

(42) After a laboratory group has vacated or a project ceased in an OGTR-certified physical containment facility, the academic or professional lead of the project or group must ensure that the area is free from hazards and GMOs, and has been fully decontaminated.

(43) Areas, equipment and surfaces that require decontamination must be identified (including bench tops, floors, surfaces of equipment, glassware and equipment such as fume hoods, biosafety cabinets, water baths, centrifuges, refrigerators, incubators, walls, sinks etc.). The appropriate disinfectant must be identified (see Appendix D – Chemical Disinfectants, of the Australian New Zealand Standards, Safety in Laboratories, Part 3: Microbiological Safety and Containment (AS/NZS 2243.3)) and used according to the standard and the manufacturer's recommendations.

(44) Where the entire facility has been vacated, all door signage must be removed from access doors if the signage is

no longer relevant to the hazards contained in the facility. In particular, the certification door signage issued by the OGTR must be removed once the certificate has been surrendered.

(45) The Senior Manager, Research Infrastructure & Biosafety (or delegate) may suspend (or lift suspension of) activity in an OGTR-certified facility, for example as a result of an identified non-compliance, or to allow maintenance or renovations to be performed. Work with hazardous infectious agents or potentially hazardous biological material is not permitted in a facility for which the certification has been suspended.

(46) All documentation must be retained with the Institute/College for eight years.

Part E - Assessment and Conduct of GMO Dealings

(47) Dealings are classified based on the level of risk to the researcher, community and environment. The level of regulatory scrutiny is proportional to the level of risk. At VU all classes of dealings must be reviewed by the IBC prior to commencement. The three main classes of dealings are:

a. Exempt Dealings
b. Notifiable Low Risk Dealings (NLRD)
c. Licensed Dealings

(48) Detailed descriptions of each class and corresponding application forms are available on the Biosafety & Biocontainment SharePoint site.

Determining the Classification of GMO Dealings

(49) The Primary/Chief Investigator overseeing the project must first determine the correct classification of the proposed GMO dealing(s) by referring to the Gene Technology Regulations 2001 (Cth), Schedules 2 and 3.

Project Application Involving GMOs

(50) All GMO dealings must be assessed by the IBC.

(51) No GMO dealing is to commence until the Primary/Chief investigator overseeing the project receives written notice from the IBC stating that the dealing can commence.

(52) The IBC requires that the GMO applications are signed by the person responsible for the facility(s).

(53) The names, qualifications, experience and training level of all key research staff must be provided.

(54) The University requires that all GMO applications by researchers are to be approved by the IBC.

(55) The Primary/Chief investigator overseeing the project must use the relevant OGTR project application form when applying to the IBC for an assessment of projects involving Exempt dealings and/or NLRDs. Application forms should be downloaded from the Biosafety & Biocontainment SharePoint site to ensure the latest version of the form is used.

(56) Applications must be in MS Word and sent via email to the Senior Officer, Animal Ethics & Biosafety from the Primary/Chief Investigator. The signatures page can be scanned and sent as a separate pdf file, if required.

(57) Where a researcher has a grant application approved through the University, but has their GMO work assessed by an IBC other than the University's IBC, the University's IBC must be notified of the nature of the project.

(58) For any dealing involving a Dealing Not Involving Release (DNIR), the OGTR DNIR application process must be followed. DNIR applications must only include information about the DNIR. Any GMOs part of the research that are classified as an Exempt Dealing or NLRD must be assessed separately using the appropriate application. The

Primary/Chief Investigator managing the project must not commence, or allow anyone else to commence, any GMO dealing without obtaining the written assessment of the project from the IBC for Exempt Dealings and NLRDs, and/or receiving the DNIR licence from the OGTR.

Obtain Assessment for GMO Dealings

(59) Completed GMO application forms should be submitted to the Senior Officer, Animal Ethics & Biosafety. The IBC OGTR Notification of Exempt Dealing Form and IBC OGTR Application for a NLRD PC1 & PC2 Form must be downloaded from the Biosafety & Biocontainment SharePoint site to ensure the latest version of the form is used. Application forms for DNIRs must be downloaded from the OGTR DNIR application process website.

(60) Applications for Exempt Dealings will be forwarded to an individual IBC member who has expertise in the relevant area. Once assessed, the Primary/Chief Investigator managing the project should receive the notice of the IBC Assessment within a few weeks of submission, depending on whether further information is required. The information will also be provided to the delegated licensee (Deputy Vice-Chancellor, Research & Impact (DVC-RI)).

(61) Applications for NLRDs and DNIRs must be assessed by the full IBC, as described in the Gene Technology Regulations 2001 (Cth).

(62) NLRD applications will be assessed at the IBC meeting and the Primary/Chief Investigator should receive the Notice of the IBC Assessment within a few weeks of the meeting, depending on whether further information is required. The information will also be provided to the delegated licensee (Deputy Vice-Chancellor, Research & Impact (DVC-RI)).

(63) DNIR application forms must be submitted to the Senior Officer, Animal Ethics & Biosafety for assessment by the IBC and monitoring by the delegated licensee (Deputy Vice-Chancellor, Research & Impact (DVC-RI)). Applications are then forwarded to the OGTR for the issuance of a license. It will take up to 90 working days after the date of submission for the OGTR to issue the license, and may take longer if further information is required.

Conduct of GMO Dealings

(64) The Primary/Chief investigator must ensure that their GMO dealings are conducted in accordance with the IBC-assessed conditions, the OGTR Guidelines, and any OGTR-imposed license conditions. Procedures must comply with the Facility Safety Manual (or equivalent) for each facility in which the dealings are conducted.

(65) The Primary/Chief investigator must manage all Occupational Health and Safety (OHS) risks of their project in accordance with the University's Risk Management Policy and Risk Management Procedure, relevant Biosafety Procedures and guidelines (available via the Policy Library and the Biosafety & Biocontainment SharePoint site), and AS/NZS 2243.3.

(66) Records of IBC assessment must be kept for eight years from the date of assessment. NLRDs must be reassessed every five years, at which stage a new application is required by the OGTR regulations. Exempt dealings approval is indefinite or until such time the regulations change.

Annual/Final Project Reports

(67) Primary/Chief Investigators must submit an IBC Annual Progress Report to the IBC as a condition of project approval. Primary/Chief Investigators who fail to submit an annual progress report may have their approval revoked.

(68) Primary/Chief Investigators must submit an IBC Final Report within three months of the expiry date or conclusion of their project as a condition of project approval. Final reports are reviewed by the IBC and kept by the University as an official record for eight years.

(69) Annual Progress Report Forms and Final Report Forms are available on the Biosafety & Biocontainment

SharePoint site.

Amendments and Variations of Projects or GMO Licence

(70) Amendments or variations to approved GMO projects are not permitted under the OGTR Guidelines. Primary/Chief Investigators are encouraged to, where appropriate, use non-limiting language in their application, that will permit the use of, for example, alternate expression systems or cloning vectors.

(71) The IBC must be notified in writing as soon as possible of any changes to an Exempt Dealing or NLRD project, as it was described in the original application for assessment by the IBC. This might include changes to key staff, the addition of a similar GMO, altered facility conditions or storage locations. Any changes must be assessed by the IBC against the original approval. Where the change is not covered within the existing approved project, a new application will need to be made prior to commencing any work under the changed conditions.

(72) Any variation, transfer or suspension of a DNIR licence must be made in writing to the Regulator by the Senior Manager, Research Infrastructure & Biosafety, and following approval by the IBC. The proposed change must not be implemented until written approval is received, which may take up to 90 days from the date of submission. Please contact the Senior Manager, Research Infrastructure & Biosafety in the first instance to assist and ensure that the correct channels are followed.

Part F - Transport, Supply, Storage & Disposal of GMOs

(73) Please see the Biosafety - Importing and Exporting Biological Material Procedure and the Biosafety - Packaging and Transport of Biological Materials Procedure. In brief:

a. All GMOs must be transported in accordance with the OGTR Guidelines for the Transport, Storage and Disposal of GMOs and may include specific licence conditions. This requires that GMOs are packaged and handled in a manner that ensures their containment throughout the transport process.
b. Transport may also require the inclusion of the Infectious Substances Dangerous Goods 6.2 symbol and the relevant UN number, and compliance with AS 4834, IATA Dangerous Goods Regulations & United Nations Recommendations on the Transport of Dangerous Goods.
c. A documented accounting process must be implemented to ensure that all GMOs that have been sent are received at the correct delivery point.
d. Before requesting any GMO to be supplied, the Chief Investigator managing the project must ensure that the correct certifications, assessments, controls and licences are in place (including import permits). The source of the supply should be included on the GMO Application form and in the Request to Import Biological Material Form.
e. Where a DNIR licence is applicable, it must not be supplied to another party unless it is a condition of the licence. Variations can be requested if there is a need to supply when it is not a condition of the current licence.
f. Primary/Chief investigators in both the receiving and requesting facility or organisation must ensure that the correct approvals (i.e. NLRD, OGTR licence etc.) are in place to hold, use, transport and supply GMOs.
g. Primary/Chief investigators must maintain records relating to GMO supply, receipt, storage and disposal.

Storage and Disposal of GMOs

(74) Primary/Chief investigators must ensure that storage of GMOs complies with requirements of the OGTR Guidelines for the Transport, Storage and Disposal of GMOs. Storage must be restricted to authorised GMOs, that is, those covered by a current assessment or licence.

(75) Unauthorised GMOs or GMOs not covered by a current IBC assessment must be destroyed.

(76) All GMOs must be labelled and stored in a safe and secure manner that prevents unauthorised access, mix-up, or

inadvertent release. Specific requirements for storage of GMOs are detailed in the OGTR Guidelines for Certification of Physical Containment Facilities, such as Level 2 Laboratory, Level 2 Animal Facility, or Exempt Dealings.

(77) Technical Managers and/or the Manager, Animal Facility must maintain records of GMO storage in the facility. The location of GMO storage units must be included in the GMO application if the storage is not within the certified facility.

(78) GMOs from Exempt Dealings and NLRDs must be disposed of in accordance with the OGTR Guidelines for the Transport, Storage and Disposal of GMOs. DNIR disposal must meet the requirements of the license.

Part G - Maintenance of Gene Technology Records

(79) Gene technology records must be maintained and be made available for inspection and audit. The following gene technology records must be maintained:

a. Research Services & IBC
    i. Minutes of meetings, correspondence, applications considered and findings, facility inspections and corrective actions, register of certified facilities, register of approved projects, gene technology hazards/incidents and recommendations/actions, internal and external reporting.
b. Institutes/Colleges
    i. Gene technology risks and risk controls must be incorporated into the local OHS Hazard and Risk Register.
c. Technical Managers / Manager, Animal Facility
    i. Facility certification and any approved variation, register of GMO dealings conducted in the facility, register of authorised staff and evidence of training/competency, register of authorised GMOs stored in the facility.
    ii. Validation and calibration of autoclaves, biosafety cabinets, waste disposal and chemicals used to decontaminate GMOs.
d. Primary/Chief Investigators directly responsible for end-users
    i. Project assessments and any variation, supply and receipt of GMOs, register of stored GMOs for projects.

Part H - Non-Compliance, Adverse Incidents & Compliance Monitoring

Non-Compliance & Adverse Incidents

(80) Please see Biosafety - Non-Compliance and Adverse Incidents Procedure. In brief:

a. Non-compliances may relate to the structural or physical attributes of an internally certified facility, to the work practices and/or the behaviour of personnel. The University, via the IBC, must notify the OGTR if it identifies any non-compliance with the conditions of accreditation, facility certification or project approval. Failure to rectify non-compliances by the clearance dates may result in the certification of the facility being suspended or revoked. The IBC and/or Senior Manager, Research Infrastructure & Biosafety may recommend to the Deputy Vice-Chancellor, Research & Impact (DVC-RI) via the Executive Director, Research Services, to suspend or revoke a certification, or close a facility, if: repeated or serious non-compliances are observed, or non-compliances are not remedied by the clearance date.
b. All adverse incidents (and near misses) must be reported via the OHS portal. OHS must provide the IBC with a report of all incidents involving biologicals or occurring in containment laboratories.
c. All biohazardous adverse incidents (and near misses) or non-compliant (or suspected non-compliant) incidents involving GMOs must be immediately reported to the IBC by calling the IBC Emergency Phone (0481 001 329). Types of incidents include non-contained spills of GMOs or potentially hazardous biological material, all

laboratory acquired infections, breach of containment and escape of transgenic animals.

d. The IBC will formally investigate and seek a written explanation of the incident from the Primary/Chief Investigator (or other relevant persons) on the incident using the IBC Incident Report Form.

Compliance Monitoring

(81) The Senior Manager, Research Infrastructure & Biosafety monitors compliance with this Procedure.

(82) The IBC must provide an annual report on biosafety to the Executive Director, Research Services for reporting to the relevant committee of Council.

(83) The University is subject to monitoring and audit by the OGTR and must submit an Annual Report to the Gene Technology Regulator.

Section 5 - HESF/ASQA/ESOS Alignment

(84) HESF: Standards 2.3 Wellbeing and Safety; 4.1 Research; 4.2 Research Training; 5.2 Academic and Research Integrity.

Section 6 - Definitions

(85) Institutional Biosafety Committee (IBC): is a Governance committee of the University, established in accordance with written guidelines issued by the OGTR under the Gene Technology Act. The IBC provides advice, resources and facilities as are necessary for safe laboratory practices.

(86) Office of the Gene Technology Regulator (OGTR): established by the federal government to support the Gene Technology Regulator administer the national regulatory system for gene technology as set out in the Gene Technology Act 2000 (the Act). The Act and Gene Technology Regulations 2001 (Cth) (the Regulations), in conjunction with corresponding State and Territory legislation, underpin the national scheme for the regulation of live and viable GMOs in Australia (including GM microorganisms) GM animals and GM plants.

(87) Licensee: The person named on the Victoria University licenses and accreditation applications as the license holder.

(88) Competent Person: A person who has acquired through training, qualification or experience the knowledge and skills to carry out the task.

(89) Dealing: any activity involving a GMO. Dealings are described as either an Exempt Dealing, a Notifiable Low Risk Dealing (NLRD), a Dealing Not Involving Release (DNIR) or a Dealing Involving Release (DIR). Dealings include:

a. conduct experiments with the GMO;
b. make, develop, produce or manufacture the GMO;
c. breed the GMO (includes housing of GMO);
d. propagate the GMO;
e. use the GMO in the course of manufacture of a thing that is not the GMO;
f. grow, raise or culture the GMO (includes storage of GMO);
g. import the GMO;
h. transport the GMO;
i. dispose of the GMO (includes decontamination process);

and includes to possess, supply, or use the GMO for the purposes of, or in the course of, a dealing mentioned in any of

paragraphs (a) to (i).

(90) Genetically Modified Organism (GMO): defined as:

a. an organism that has been modified by gene technology;
b. 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;
c. anything declared by the Regulations to be a genetically modified organism, or that belongs to a class of things declared by the Regulations to be genetically modified organisms; but does not include:
    i. a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy;
    ii. an organism declared by the Regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the Regulations not to be genetically modified organisms.

The Regulations provide specific definitions for genetically modified guinea pigs, mice, rabbits and rats.

(91) Gene Technology: Any technique for the modification of genes or other genetic material. It does not include:

a. sexual reproduction;
b. homologous recombination;
c. any other technique specified in the Regulations for the purposes of this paragraph.

NB: All work involving Gene Editing Technologies (e.g., CRISPR /Cas9 system), must be reviewed by VU's IBC via the high-risk project application process. Note that amendments to regulations, effective February 2025, introduced the following:
– Organisms modified using SDN-1 (site-directed nuclease with unguided repair, i.e., no nucleic acid template added) are not classified as GMOs under Schedule 1 of the Regulations.
- If CRISPR/Cas9 is used in a way that introduces a template or other genetic material, the organism is regulated as a GMO.
- Intermediate steps that involve GMOs (e.g., transient expression of Cas9 from a cassette) still require authorisation while those components are present.

Status and Details

Status	Current
Effective Date	8th December 2025
Review Date	8th December 2028
Approval Authority	Deputy Vice-Chancellor, Research & Impact
Approval Date	7th December 2025
Expiry Date	Not Applicable
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