Low Risk Genetically Modified Dealings Procedure

Section 1 - Purpose and Scope

(1) This Procedure outlines requirements at The University of Queensland (UQ) for conducting work (a 'dealing') with genetically modified organisms (GMOs) that are classified as Exempt Dealings or Notifiable Low Risk Dealings (NLRD) under the Gene Technology Act 2000. The definition of a 'dealing' for the purposes of this Procedure is provided in the appendix. This Procedure supports UQ's Biosafety Policy and outlines the requirements UQ workers must meet to comply with gene technology regulation.

(2) This Procedure does not include higher risk dealings that require a Dealing Not involving Intentional Release (DNIR) of the GMO into the environment or a Dealing involving the Intentional Release (DIR) of a GMO into the environment. Contact HSW Biosafety on biosafety@uq.edu.au for further information.

(3) This Procedure applies to all staff, students, visitors, volunteers, and contractors (UQ workers) conducting dealings with GMOs at UQ's St Lucia, Dutton Park, Gatton, and Herston campuses and associated working areas (including Long Pocket, Greenslopes Hospital, and the Translational Research Institute).

(4) This Procedure should be read in conjunction with the UQ Biosafety Policy that apply to genetically modified (GM) dealings.

Context

(5) The Australian Government regulates GMOs under the Gene Technology Act 2000 (the Act), which provides that all Dealings with GMOs are prohibited unless they are classified otherwise. The Office of the Gene Technology Regulator (OGTR) administers requirements of the Act and classifies materials based on risk to the health and safety of people and the environment.

(6) Exempt Dealings and NLRDs are categories of Dealings with GMOs that have been assessed by the OGTR as posing very low to low risk provided certain risk management conditions are met. It is a legislative requirement that Exempt Dealings and NLRDs must not involve an intentional release of a GMO into the environment.

(7) The Gene Technology Regulations 2001 (the Regulations) provide descriptions of Exempt Dealings, NLRDs and host/vector systems that have been classified by the OGTR. Links to these are also provided in the appendix.

(8) Further information about the regulation of GMOs in Australia is available from the Health, Safety and Wellness Division's Biosafety Advisors or the OGTR's website.

Section 2 - Process and Key Controls

(9) UQ workers must comply with the following measures when conducting Dealings with GMOs:

a. Prior to dealing with GMOs, UQ workers must follow appropriate risk management procedures and be properly trained (includes online Biosafety training and specific training determined by the supervisor) and deemed competent by their supervisor to work with GMOs.
b. Honour students, volunteers and visitors from other institutions must always be supervised while undertaking a

NLRD with a GMO or Genetically Modified (GM) material if they have not completed the appropriate training. Once the training has been completed and they are deemed competent by their supervisor, they may work with limited supervision.

c. Exempt Dealings may be conducted in a facility that meets the standard of a Certified Physical Containment Level 1 (PC1) facility as describe in AS/NZS 2243.3:2022 Safety in Laboratories - Microbiological Safety and Containment (available via Standards Databases through UQ Library) for specific hazards and control measures).
d. NLRD must be performed in a PC1 or higher as appropriate to the risk group classification of the material.
e. Chief Investigators are primarily responsible for the oversight of Exempt Dealings and NLRD with GMOs, including the application process and ongoing management of the dealing.

Undertaking NLRD

(10) The IBC delegates the assessment of the NLRD to the Institutional Biosafety Sub-Committee (IBSC).

(11) Prior to undertaking any NLRD with GMOs, the applicant must submit an NLRD application through UQSafe and the application must be approved by the IBSC. Exempt Dealings may also be included in a NLRD application.

(12) The HSW Biosafety Team prepares the Records of Assessment for the NLRD on behalf of the IBSC and provides it to the Chief Investigator.

(13) The Records of Assessment must be in a form that meets the requirements of Section 13B of the Regulations.

(14) Details of the NLRD must be provided to the OGTR in a form determined by the Regulator within the timeframes stipulated in the Act.

Undertaking Exempt Dealings

(15) The IBSC delegates the assessment of Exempt Dealing applications to the HSW Biosafety Team.

(16) Prior to undertaking Exempt Dealings with GMOs, the applicant must submit an Exempt application through UQSafe and the application must be approved by the IBC.

(17) The Exempt Dealing applications will be assessed to ensure that they do not include any NLRD or higher risk dealings. Any applications not meeting the conditions of an Exempt Dealing will be rejected.

(18) If research groups have a previous NLRD approval or are going to apply for an NLRD that will include identical Exempt Dealings, then a separate Exempt application is not required to be submitted. The approval for the Exempt Dealings will be included in the NLRD.

Section 3 - Key Requirements

Training and risk management

(19) Before conducting any dealing with GMOs, UQ workers must:

a. undertake the appropriate induction training as required (refer to the HSW New Worker Induction Checklist in Workday);
b. complete a risk assessment(s) and be familiar with any standard operating procedure/s; and
c. comply with the conditions stipulated in the IBC's approval of the dealing and the Records of Assessment.

Application process for NLRDs

(20) Before undertaking an NLRD, the Chief Investigator or a delegated responsible person, must complete and submit a NLRD application using the Lab Activity Application Register in UQSafe.

(21) Sufficient information must be provided within the application to allow the IBSC to determine whether the proposed dealing meets the relevant classification criteria.

(22) NLRD cannot be varied under the Regulations. Any changes to NLRD must be reassessed and approved as a new NLRD application by an IBC, in accordance with regulatory requirements.

Approval process

(23) Applications are assessed by the IBSC members with the relevant skills, knowledge or experience.

(24) The members must assess NLRD applications based on the following:

a. Completeness and accuracy of the application;
b. The application meets the requirements of Schedule 3 of the Regulations;
c. Transport, storage and waste management meet the Regulator's guidelines, University's policies, procedures and guidelines and the hazard presented by the organism;
d. Risk Assessment(s) address the hazards encountered in the dealings;
e. Sufficient controls of all foreseeable hazards associated with the dealings are in place;
f. Refer the applicant to any vaccination requirements.;
g. Other permits or approvals required for the proposed work;
h. The classes of person permitted to undertake the dealings; and
i. The classes of facilities are assessed as suitable for the dealings.

(25) Where the UQ IBC acts as the IBC for external organisations, the classes of people assessed for such applications will be on a case-by-case basis. The classes assessed will be mentioned in the Record of Assessment.

Facilities

(26) Dealings with GMOs must be conducted in facilities approved for the proposed dealings.

(27) Exempt Dealings are not required to be carried out in OGTR-certified facilities but must be carried out in a facility that is appropriate for the risk group of the material being used (i.e. PC2 for risk group 2 material).

(28) All NLRD must be conducted within OGTR-certified facilities.

(29) Dealings requiring containment as specified in Schedule 3 must be conducted, at least, in OGTR-certified facilities appropriate to the required containment level: PC1 dealings in PC1 facilities, PC2 dealings in PC2 facilities, and NLRD dealings involving GM Risk Group 3 organisms or materials (as per AS/NZS 2243.3:2022 Safety in Laboratories - Microbiological Safety and Containment) in PC3 facilities.

(30) The Chief Investigator must ensure that the facility where the NLRD is conducted holds a current OGTR certification. This can be verified by checking the expiry date on the OGTR certification label located on each access door.

(31) If a facility label has expired, all work with GMOs, other than storage, must cease and the HSW Biosafety must be notified immediately.

(32) If biological material generated in a PC2 facility is intended to be transferred to a PC1 facility, this must be

detailed in the NLRD application for assessment. If approved, the conditions permitting such movement will be outlined in the Record of Assessment.

(33) If non-UQ facilities are to be used by UQ workers for any Exempt Dealing or NLRD, approval/acknowledgement must be sought from the appropriate facility manager. HSW Biosafety will confirm with the Research Groups to ensure that these approvals are in place prior to application approval.

(34) All external facilities will be listed in the NLRD Record of Assessment.

(35) UQ workers conducting dealings in non-UQ facilities are expected to follow UQ requirements as well as facility-specific requirements applicable to GM work undertaken (for example complete UQ Biosafety training as well as any training specified by the Accredited Organisation responsible for the non-UQ facility). Users are to check with HSW Biosafety if there are any instances where conflicts are noted.

(36) When external parties such as waste disposal contractors or transport couriers handle GMOs, GM material, or GM waste during UQ-related dealings at non-UQ facilities, the accredited organisations managing those facilities are expected to ensure these individuals meet the relevant training requirements.

Reporting Breaches

(37) Chief Investigators and UQ workers are responsible for monitoring all aspects of an Exempt Dealing or a NLRD they are authorised to undertake. Any actual or potential breaches of conditions associated with the use, storage or handling of GMOs must be reported as soon as practicable to UQ Biosafety Advisors on biosafety@uq.edu.au.

(38) The UQ Biosafety Advisors are responsible for reporting breaches or potential breaches to the OGTR.

Section 4 - Roles, Responsibilities and Accountabilities

Institutional Biosafety Committee (IBC)

(39) The IBC delegates the assessment of Low Risk Genetically Modified Dealings to the IBSC.

Institutional Biosafety Sub-Committee (IBSC)

(40) The IBSC will undertake duties in accordance with its Terms of Reference and the Biosafety Policy. The IBSC's responsibilities include:

a. Assisting Chief Investigators determine classification of GMO dealings.
b. Producing and approve a valid Record of Assessment compliant with Section 13B of the Gene Technology Regulations 2001.
c. Report to the Institutional Biosafety Committee (IBC) of the outcomes of its meetings.

Health, Safety and Wellness Division (HSW Division)

(41) The Health, Safety and Wellness Division is responsible for:

a. Providing UQ workers with education, advice and support regarding OGTR requirements and gene technology regulatory compliance obligations at UQ.
b. Assessing whether Organisational Units and UQ workers can demonstrate compliance with this Procedure and that any compliance issues identified are rectified in a timely manner.

(42) Biosafety Advisors within the HSW Division are responsible for:

a. Providing UQ workers with education, information, and support to enable them to understand their biosafety compliance obligations at UQ.
b. Assessment and approval of Exempt Dealings.
c. Reporting to or advising UQ's IBC and IBSC on gene technology matters as required.
d. Liaising with the OGTR with respect to UQ's gene technology and GMO dealings compliance obligations (including hosting regulator site visits or inspections).
e. Act as the Secretary of the IBSC, complete and provide the Record of Assessment to the Chief Investigators and prepare the annual report to the OGTR.
f. Report breaches and contraventions of the OGTR legislation, guidelines and instruments as they relate to GMO dealings to the OGTR.

Heads of Organisational Units Authorised to Undertake Dealings

(43) Heads of Organisational Units that undertake dealings with GMOs must work with Chief Investigators to ensure containment facilities are compliant with OGTR requirements, including:

a. Facilities appropriate for the type of work are available and maintained in compliance with the relevant legislative requirements (e.g. PC2 certified facilities maintained to OGTR certification requirements, including funding and arrangements for maintenance, routine testing and servicing); and
b. Any work with material meeting Exempt Dealing or NLRD classification is conducted in compliance with requirements detailed in the Act and Regulations, associated facility certification guidelines or IBC approvals (e.g. GM work has appropriate approvals in place before commencing, all UQ workers have completed appropriate training prior to commencing work).

Chief Investigators

(44) Chief Investigators are responsible for the ongoing monitoring, management and oversight of Exempt Dealings and NLRDs, and must ensure:

a. An Exempt Dealing or NLRD approved by the IBSC is in place prior to commencing work with the GMO.
b. Ensure that the dealings with GMOs comply with the conditions of the IBSC's approval and are conducted in a certified Physical Containment facility appropriate for the risk group of the material being used (i.e. PC2 for risk group 2 material) and that the facility is currently certified.
c. Ensure that the facility where the dealings are conducted holds a current OGTR certification. This can be verified by checking the expiry date on the OGTR certification label located on each access door.
d. Ensure that the dealings with GMOs are within the scope of the IBSC approval, and if any deviation is anticipated, new approvals sought before attempting such work. Manage the risks associated with the dealings.
e. Exempt Dealings and NLRDs are reviewed and extended or closed where necessary.
f. Records are maintained in accordance with facility certification or IBSC approval requirements.
g. Inform UQ's Biosafety Advisors if movement to another facility not listed on the approval is required.
h. Train UQ Workers, facility managers and other relevant persons with the details and conditions of approvals.
i. Report any noncompliance or contravention of the approve dealing to Biosafety as soon as practicable.
j. All UQ workers handling GMOs are trained in accordance with OGTR requirements and comply with IBSC and facility approval conditions, including supervising individuals not authorised to work unsupervised with GMOs.

UQ Workers

(45) All UQ workers undertaking Exempt Dealings or NLRD with GMOs at UQ must comply with this Procedure,

understand, and comply with any additional requirements specified by OGTR, and ensure they are:

a. Following the requirements for the facility being worked in (i.e. complete relevant training, comply with PPE requirements etc.);
b. Read the GMO applications, risk assessments and understand all conditions of approvals that are in place for the work they are conducting;
c. Ensure they are the approved class of person in the approval and that the dealing is in an approved class of facility as listed in the UQSafe application;
d. Ensure the facility is currently certified as per the access door label;
e. If it is determined that they do not meet the conditions of clause 45(c) and (d), they must stop work and report the issue to the Chief Investigator immediately.

(46) UQ workers handling, using, or storing GMOs at locations external to UQ, must comply with the local procedures and requirements of the external organisation.

Section 5 - Monitoring, Review and Assurance

Compliance

(47) UQ Biosafety Advisors will provide ongoing monitoring and review of UQ's biosafety systems and controls on behalf of the IBC. This includes annual audits and inspections of OGTR certified facilities where low risk dealings are undertaken, renewal of any associated facility certifications, and renewal of any associated licences. UQ Biosafety Advisors will review this Procedure as required to ensure it remains current and accurately reflects regulatory requirements.

Non-compliance

(48) UQ workers and Chief Investigators that do not comply with this Procedure may be subject to corrective actions from the IBC.

(49) UQ may be subject to corrective actions or notices issued by the OGTR to suspend work that does not comply with regulatory requirements.

Section 6 - Recording and Reporting

(50) The IBSC provides a Record of Assessment to the Chief Investigator that meets the requirements of Section 13B of the Gene Technology Regulations 2001.

(51) Chief Investigators must ensure that the record-keeping requirements of approved Exempt Dealings and NLRDs meet the requirements and conditions of the Act, Regulations and UQ procedures.

(52) Information collected from Chief Investigators' applications to the IBCmay be provided to the OGTR for auditing purposes if required.

(53) UQ Biosafety Advisors will report outcomes of audits of OGTR certified facilities where Exempt Dealings and NLRDs are undertaken to the IBC on a regular basis (e.g. at each scheduled IBC meeting) and the IBC will report any non-compliances or potential breaches to UQ Senior Management and for the relevant area.

(54) The Biosafety Advisors are responsible for reporting any matters required by the Act or Regulations, approvals, or licences to the OGTR.

Section 7 - Appendix

Definitions, terms and acronyms

Terms	Definitions
Accredited organisation	The Gene Technology Regulator requires organisations undertaking certain dealings with genetically modified organisms (GMOs) to be accredited. Accreditation details can be found at the Organisation accreditation requirements webpage.
Authorised Classes of Persons	For the purposes of undertaking a dealing with a GMO or GM material, the following classes of persons must be supervised at all times while working – undergraduate students, volunteers, visitors who have not completed online biosafety training.
Chief Investigator	For the purposes of this Procedure includes Supervisors, Managers, Project Leaders and academic principal advisors that are conducting research at UQ and hold an academic or research appointment.
Classes of Person	Classes of person include: a. Chief Investigator b. Scientists and other research staff c. Laboratory/facility/operations managers d. Professional / technical / support / staff (including central facilities, autoclave / wash-up facility staff) e. Biosafety contacts / Safety Team members f. Waste service contractors g. Transport service providers For the purposes of undertaking a dealing with a GMO or GM material, the following classes of persons must be supervised at all times while working – undergraduate students, volunteers and visitors who have not completed online biosafety training.
Classes of Facilities	Classes of facilities include all OGTR certified facilities (PC1, PC2, PC3 and PC4) including: a. Laboratory b. Animal c. Aquatic d. Invertebrate e. Plant.
Dealing	In relation to a GMO, 'dealing' is defined in the Act 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.
Exempt Dealing	A category of dealing with GMOs that has been assessed over time as posing a very low risk (i.e. contained research involving very well understood organisms and processes for creating and studying GMOs). See Schedule 2 of the OGTR regulations: Types of dealings exempt from licensing.
Exempt host / vector systems	A host/vector system refers to a combination of a host organism and a vector used to introduce genetic material into the host.
Genetically Modified Organism (GMO)	Any plant, animal, or microorganism whose genetic material (DNA) has been altered using genetic engineering techniques in a way that does not occur naturally through mating or recombination.
UQ's Institutional Biosafety Committee (IBC)	A body that oversees and regulates research and other activities involving biological materials, particularly those classified as biohazards or genetically modified organisms (GMOs).

Terms	Definitions
UQ's Institutional Biosafety Sub-Committee (IBSC)	A sub-committee of the IBC who has delegated powers from the IBC.
Notifiable Low Risk Dealing	A category of Dealing with GMOs that has been assessed over time as posing a low risk (i.e. contained research not released into the environment) provided certain risk management conditions are met. See Schedule 3 of the OGTR regulations: Types of dealings with GMOs classified as Notifiable Low Risk Dealings (NLRDs).
Office of the Gene Technology Regulator (OGTR)	This Australian Government body is responsible for administering the country's gene technology regulatory system, which aims to protect public health and the environment by managing risks associated with genetically modified organisms (GMOs). The OGTR assesses applications for the use of GMOs and issues licenses, making sure that these activities are conducted safely and according to the law.
Guidelines for the Transport, Storage and Disposal of GMOs	Transport, storage, and disposal of genetically modified organisms (GMOs) require strict containment measures to prevent accidental release, including sealed primary and secondary packaging, secure storage in designated physical containment facilities, and decontamination before disposal through designated biohazard waste streams. Labelling is crucial, with primary containers identified and secondary units showing responsible person details. All activities must comply with the Office of the Gene Technology Regulator (OGTR) Guidelines for the Transport, Storage and Disposal of GMOs and facility-specific procedures.
UQ Workers	For the purposes of this Procedure includes: - UQ staff, including continuing, fixed-term and casual staff; - contractors, subcontractors and consultants; - students enrolled at UQ, including post graduate researchers, Higher Degree by Research students and undergraduate students; - visiting academics and researchers; - visiting research students; and - volunteers engaged by UQ that may be required to handle OGTR regulated material.

Status and Details

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