Release of Gene-Edited Plant Material from GMO Regulatory Control Procedure

Section 1 - Purpose and Scope

(1) This Procedure outlines requirements at The University of Queensland (UQ) for releasing plant material from genetically modified (GM) dealing conditions for use in non-certified facilities or in the field.

(2) Gene edited material refers to a plant, or any part of a plant, seed, tissue culture, propagule, or progeny thereof, that has had its genome modified. It is produced by using site-directed nuclease techniques and was generated using a method in which the editing reagents were delivered via a transgene, such that the organism passed through an intermediate genetically modified organism (GMO) state.

(3) Gene edited material as defined above is deemed a genetically modified organism (GMO) for the purposes of this Procedure and must be handled in accordance with UQ's GMO/biosafety requirements and any applicable Office of the Gene Technology Regulator (OGTR) licence, Dealing Not Involving Intention Release (DNIR), or Notifiable Low Risk Dealing (NLRD) conditions, unless and until it is released from GMO regulatory control in accordance with this Procedure.

(4) This Procedure does not apply to material edited using DNA-free or transgene-free delivery methods that did not involve an intermediate GMO state. Such material falls outside the scope of this Procedure, and its GMO status, must be determined separately under the Gene Technology Act 2000 (Cth) and the Gene Technology Regulations 2001 and UQ policies.

(5) This Procedure applies to all staff, students, visitors, volunteers, and contractors (UQ workers) working with gene-edited plant material following release from GM dealing conditions at UQ campuses, sites and facilities and at non-UQ sites where the dealings are approved by the University of Queensland Institutional Biosafety Committee (IBC).

(6) This Procedure supports UQ's Biosafety Policy and should be read in conjunction with other relevant procedures that apply to GM dealings (e.g. Low Risk Genetically Modified Dealings Procedure).

Context

(7) The Australian Government regulates genetically modified organisms (GMOs) under the Gene Technology Act 2000 (the Act), which states that all dealings with GMOs are prohibited unless they are classified otherwise.

(8) The OGTR administers requirements of the Act and classifies materials based on risk to the health and safety of people and the environment.

(9) The Gene Technology Regulations 2001 (the Regulations) provide descriptions of Exempt Dealings (ED), NLRD and host/vector systems that have been classified by the OGTR.

(10) The Regulations provide descriptions of organisms that are not considered genetically modified including those that were generated through gene modification techniques (Schedule 1), i.e. gene-edited plant material released from GM dealing conditions.

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

Section 2 - Key Controls

(12) UQ workers must comply with the following measures when working with gene-edited plant material at UQ:

a. Follow appropriate risk management procedures, be properly trained (UQ online Biosafety training and specific training determined by the Supervisor) and assessed competent by their Supervisor to work with GMOs.
b. Have protocols in place for ensuring the release of viable GMOs from containment will not occur.
c. Undergraduate students, volunteers and visitors must be supervised by a UQ worker authorised by UQ's Institutional Biosafety Committee (IBC) while undertaking a dealing with a GMO or GM material.

(13) Before work with gene-edited plant material can be released from GM dealing conditions, approval must be obtained from UQ's Institutional Biosafety Sub-Committee (IBSC) to ensure the proposal complies with the relevant classification criteria.

(14) Chief Investigators are responsible for the oversight of work with gene-edited plant material released from GM dealing conditions, including the application process and ongoing management of the dealing.

(15) Protocols, procedures and records of the release from GM dealing conditions, must be kept and presented to the IBC or Regulator upon request.

Section 3 - Process and Key Requirements

Training and Risk Management

(16) Before conducting any work with gene-edited plant material released from GM dealing conditions, UQ workers must:

a. undertake the appropriate induction training as required (refer to the staff health and safety training and induction website and the Inductions and Training Needs Assessment Checklist);
b. complete a risk assessment(s) and familiarisation with any standard operating procedures;
c. obtain approval from the UQ IBSC (if applicable); and
d. comply with the conditions stipulated in the IBSC's approval of the work (if applicable).

Approval Process

(17) Currently, only Agrobacterium mediated transform plants are eligible to be released.

(18) Work with gene-edited plant material released from GM dealing conditions must not commence at UQ without prior UQ IBSC approval, unless expressly permitted by this Procedure.

(19) Application to work with gene edited material released from GM dealing conditions must be made to the IBC by the Chief Investigator by writing to the IBSC Chair.

(20) The Chief Investigator must demonstrate the plant is free from transgenes by:

a. Confirm that the transformation was performed using Agrobacterium mediated process and that the method was SDN-1 (no template was used).

b. Provide the vector and T-DNA sequence.
c. Assurance that plants have been isolated to ensure that no cross pollination with other GM plants has occurred.
d. Clearly identify the plants that have undergone the process.

(21) Details of the protocol used to determine the absence of transgenes:

a. Primer identifiers.
b. Polymerase Chain Reaction (PCR) cycle details (number of cycles, temperature, duration).
c. Gene of interest details.

(22) Results must demonstrate that the transgenes are absent from the Segregant. This can be in the form of an image of the electrophoresis of the PCR products.

(23) The Chief Investigator must provide sufficient information within the application to allow the IBC to determine whether the proposed dealing meets the relevant classification criteria.

(24) All approved work with gene-edited plant material released from GM dealing conditions must comply with any conditions stipulated in the IBC's approval of the work.

Compliance with gene-edited plant material requirements

(25) Chief Investigators and UQ workers are responsible for the ongoing monitoring, management and oversight all aspects of work authorised under an IBC approval to release gene-edited plant material from GM dealing conditions.

(26) In conducting work with gene-edited plant material released from GM dealing conditions, Chief Investigators must:

a. ensure that the work complies with the conditions of the IBC's approval;
b. all UQ workers handling the material is trained in accordance with OGTR requirements and comply with IBC and facility approval conditions, including supervising individuals not authorised to work unsupervised with the material; and
c. regularly monitor and review the work in line with good laboratory practices.

Reporting Breaches

(27) Any actual or potential breaches of conditions associated with the use, storage or handling of gene-edited plant material released from GM dealing conditions must be reported as soon as practicable to UQ Biosafety Advisors (biosafety@uq.edu.au).

Section 4 - Roles, Responsibilities and Accountabilities

Institutional Biosafety Committee (IBC)

(28) The IBC delegates the assessment of gene edited plant material to the IBSC.

Institutional Biosafety Sub-Committee (IBSC)

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

a. assessment and approval of applications to release gene-edited plant material from GM dealing conditions;
b. assisting Chief Investigators determine classification of work covered under this Procedure; and
c. providing UQ workers with education, information and support to enable them to understand their biosafety compliance obligations at UQ.

Chief Investigators

(30) Chief Investigators are responsible for the ongoing monitoring, management and oversight of work with gene edited material released from GM dealing conditions, and must ensure:

a. work is conducted in appropriate facilities or locations in compliance with OGTR or IBC approvals;
b. an IBC approval to release gene-edited plant material from GM dealing conditions is in place prior to releasing the material;
c. records are maintained in accordance with IBC approval requirements and UQ's Responsible Research Management Framework Policy and Research Data Management Policy;
d. use only methods of releasing gene-edited materials approved by the IBC and the OGTR.

UQ Workers

(31) All UQ workers working with gene-edited plant material released from GM dealing conditions at UQ must comply with this Procedure, understand and comply with any additional IBC requirements, and ensure they are:

a. aware of any approvals that are in place for the work they are conducting;
b. following the requirements for the facility being worked in (i.e. complete relevant training, comply with PPE requirements etc.);
c. keeping records of all work associated with gene-edited plant material; and
d. following any specific requirements listed in the approval.

(32) UQ workers handling, using or storing gene-edited plant material released from GM dealing conditions at locations external to UQ, must comply with the local procedures.

Health, Safety and Wellness Division

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

a. providing UQ workers with education, advice and support regarding requirements for working with gene-edited plant material released from GM dealing conditions and relevant regulatory compliance obligations at UQ; and
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.

(34) Biosafety Advisors within the Health, Safety and Wellness Division are responsible for:

a. advising workers about specific Biosafety matters affecting UQ, including workplace safety obligations and regulatory compliance; and
b. reporting to or advising UQ's IBC on gene-edited plant material released from GM dealing conditions as required.

Section 5 - Monitoring, Review and Assurance

(35) Chief Investigators will:

a. monitor work undertaken by workers under their supervision ensuring they comply with this Procedure and any direction or approval given by the IBC or regulatory body.
b. report to the IBC as soon as practicable if an actual or suspected non-compliance with an approval, direction, legislative instrument or guidelines is detected.

(36) UQ Biosafety Advisors will:

a. provide ongoing monitoring and review of UQ's biosafety systems and controls on behalf of the IBC; and
b. review this Procedure as required to ensure it remains current and accurately reflects regulatory requirements.

Non-compliance

(37) UQ workers and Chief Investigators that do not comply with this Procedure may be subject to corrective actions from the IBC and suspension of work if conditions are not met.

(38) 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

(39) Chief Investigators must ensure that the record-keeping requirements of UQ IBC approval to release gene-edited plant material from GM dealing conditions are met in accordance with UQ's Research Data Management Policy.

(40) UQ Biosafety Advisors will report outcomes of IBC approvals to release gene-edited plant material from GM dealing conditions 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.

(41) Non-compliances and other matters will be reported to the OGTR following the IBC reporting protocols.

Section 7 - Appendix

Definitions, Terms, Acronyms

Terms	Definitions
Chief Investigator	For the purposes of this Procedure includes Supervisors, Managers and academic principal advisors that are conducting research at UQ and hold an academic or research appointment.
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; and • possess, supply or use the GMO for the purposes of, or in the course of, any of the above.

Terms	Definitions
Gene-edited Plant Material	For the purposes of this Procedure, gene edited plant material is defined in clauses 2 to 4.
GM Dealing Conditions	Conditions issued either by the UQ IBC or the OGTR for work with GMOs either as an Exempt or Notifiable Low Risk Dealing (see Low Risk Genetically Modified Dealings Procedure), Dealing Not for Intentional Release (DNIR) or Dealing for Intentional Release (DIR).
GMO	Genetically modified organism.
IBC	UQ's Institutional Biosafety Committee.
IBSC	UQ's Institutional Biosafety Sub-Committee.
OGTR	Office of the Gene Technology Regulator (Australian Government).
UQ Workers	For the purposes of this Procedure includes: • staff – continuing, fixed-term, research (contingent funding) and casual staff members; • visiting academics and researchers; • affiliates – academic title holders, visiting academics, Emeritus Professors, adjunct and honorary title holders, Industry Fellows and conjoint appointments; and • Higher Degree by Research students.

Status and Details

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