UNIVERSITY of TASMANIA

Operations Framework for Biosafety, Biosecurity and Gene Technology

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Document control box			
Version	1.5	Approved by	University Research Committee
Status	Approved	Approval date	24/6/2020

Revision Record		
Date	Version	Revision Description

Contents

Executive Summary

Legislation relating to biosafety, biosecurity and gene technology is multifaceted, and forms part of a complex web of interactions between research providers, regulators and enforcement agencies. Successful navigation of this landscape requires a high degree of coordination and connection, particularly when managing issues affecting multiple and varied stakeholders.

Maintaining a safe work environment in facilities where biologically-hazardous materials are used is a requirement of this legislation. This is a shared responsibility; University management have a legislated duty of care to provide and maintain protective equipment and containment infrastructure, a policy relating to safe work practices, and must promote the training of those practices. University workers must complete relevant training, carry out safe work practices and use protective equipment to minimise the risk of injury or prevent illness to themselves and other workers.

This Operations Framework ('the framework') is based on the CEN Workshop Agreement for Laboratory Biorisk Management (CWA 15793:2011) and adopts a management system approach to describe a system of enmeshed controls to safely, effectively and efficiently support activities involving biosafety, biosecurity and gene technology at the University of Tasmania.

It is important to implement an operations framework in this space to ensure:

- Staff, students and visitors have a safe work environment and occupational risks are minimised;
- Risk of negative impact to Australia's primary industries, environment and society arising from research activities at the University is minimised;
- Research activities at the University can demonstrate compliance with relevant legislation and subordinate regulations;
- The University has the capacity to amend or adapt operational practices to effectively manage future technological advances in gene technology;
- Compliance is achieved with minimal administrative impost and minimal duplication of effort;
- Design, construction and refurbishment of facilities to meet regulatory requirements is effective, efficient and achieved at minimal cost;
- The University has the opportunity to contribute to the development of future legislation and regulations;
- The University exemplifies operational best practice and is a preferred provider of research services involving biosafety, biosecurity and gene technology.

To achieve these aims, the framework adopts the following overarching objective:

Objective

*To define and implement best-practices for **identifying, understanding and addressing** risks to human health, primary production and the natural environment arising from the use of gene technology, biologically-hazardous materials and imported biological materials at the University of Tasmania.*

Implementation of the framework aims to complement the strategic plans of the Research Division and the University by minimising duplication of compliance efforts and increasing the efficiency of regulatory administration. The framework is principles-based rather than prescriptive, and will be a living document to strive for continual improvement in operational practices as regulations and technology change over time.

Acronyms and Definitions

Term	Definition
ABSANZ	Association of Biosafety for Australia and New Zealand
Approved Arrangement (AA)	A biosecurity containment facility for which an approval is in force under paragraph 406(1)(a) of the *Biosecurity Act 2015* (Cth).
Approved Quarantine Place (AQP)	A place, or part of a place, that has been approved by Biosecurity Tasmania as meeting containment standards suitable for storage and use of plant material under biosecurity control.
AS 2243.3	Australian Standard 2243.3 *Safety in Laboratories – Microbiological Safety and Containment*
BICON	The Commonwealth Department of Agriculture's Biosecurity Import Conditions Online database.
Biologically-hazardous material	A microorganism which may adversely affect humans, plants and terrestrial and aquatic animals. Include organic toxins, bacteria, parasites, fungi, viruses, plant pathogens, invertebrates and aquatic organism pathogens capable of causing disease. Also known as a **biological agent**, a **biorisk** or a **biohazard**.
Biological agent	See **biologically-hazardous material**
Biorisk	See **biologically-hazardous material**
Biosafety	Principles, technology and practices that are implemented to prevent unintentional exposure to biological agents and toxins, or their accidental release.
Biosecurity	Management of risks to the Australian and Tasmanian economy, the natural environment and society from pests and diseases entering, establishing or spreading.
Biosecurity compendium	Under s.9 of the *Biosecurity Act 2019* (Tas), DPIPWE is to keep an online compendium listing all prohibited matter, permitted matter, restricted matter and explanatory or supporting information.
Biosecurity control	Obligations and regulations pertaining to material which poses a medium to high biosecurity risk as determined by the Commonwealth Department of Agriculture. Dealings with materials under biosecurity control must be performed in a certified or approved containment facility.

Biosecurity event	The presence in Tasmania, or part of Tasmania, of prohibited matter, a disease, or an invasive pest. Defined in s.10 of the *Biosecurity Act 2019* (Tas).
Biosecurity Industry Participant (BIP)	A person or organisation who is the holder of the approval of an Approved Arrangement with the Department of Agriculture under the *Biosecurity Act 2015* (Cth). The University of Tasmania is a Biosecurity Industry Participant.
Biosecurity matter	Organisms, contaminants, plant or animal products, or diseases as defined in s.12 of the *Biosecurity Act 2019* (Tas).
Biosecurity Tasmania	The Tasmanian biosecurity regulator; part of DPIPWE.
CAR	Corrective Action Request from the Department of Agriculture
CEN	European Committee for Standardisation
Containment Facility	A facility constructed to meet the standards of AS2243.3. Containment facilities may be certified by the OGTR (PC1 to PC4 level) or by the Department of Agriculture (Approved Arrangements).
CWA	CEN Workshop Agreement
DAWE	Commonwealth Department of Agriculture, Water and the Environment
Dealing	An activity performed with, or on, a genetically modified organism, biological agent or material under biosecurity control. Defined in s.10 of the *Gene Technology Act 2000* (Cwth) and s.14 of the *Biosecurity Act 2019* (Tas).
DIR	Dealing Involving Intentional Release. A dealing with a GMO which involves the intentional release of the GMO to the environment. DIRs require licencing and direct scrutiny from the OGTR, however, they are currently prohibited in Tasmania under the Genetically Modified Organisms Control Act 2004 (Tas).
DNIR	Dealing Not Involving Intentional Release. A dealing with a GMO which is conducted in a certified containment facility, but is of higher risk than an NLRD and requires licencing and direct scrutiny from the OGTR.
DPIPWE	Tasmanian Department of Primary Industries, Parks, Water and the Environment.
Entry number	A unique identifier issued by DAWE to a consignment of biosecurity material imported to Australia under the conditions of an import permit.
Gene Technology	Activities and techniques concerned with the expression of genes, selection of organisms based on genetic variation, artificial modification of genes and transfer of genes to new host organisms. Also referred to as synthetic biology.

GMO	Genetically Modified Organism. Defined specifically in the *Gene Technology Regulations 2001* (Cth).
IBC	Institutional Biosafety Committee. References in this document pertain to the University of Tasmania Institutional Biosafety Committee.
Import Permit	A permit issued by the Department of Agriculture for the import of conditionally prohibited materials to Australia.
ISO	International Organisation for Standardisation
Licenced Dealing	A DIR or DNIR which requires direct scrutiny from the OGTR.
NLRD	Notifiable Low Risk Dealing. A dealing with a GMO which does not require direct scrutiny from the OGTR but must be assessed by an Institutional Biosafety Committee. All NLRDs must be conducted in a certified containment facility.
OGTR	Office of the Gene Technology Regulator
Permitted matter	Biosecurity matter which does not pose a biosecurity risk to Tasmania or part of Tasmania. Defined in s.19 of the *Biosecurity Act 2019* (Tas).
Physical Containment (PC)	Guidelines for the design, construction and operation of biological containment facilities outlined in AS2243.3
Prohibited matter	Biosecurity matter which poses a significant biosecurity risk to Tasmania or part of Tasmania. Defined in s.20 of the *Biosecurity Act 2019* (Tas).
Regulated biological materials	Any material which may be genetically-modified, subject to regulation by an Act of Parliament or subordinate regulation (including Biosecurity Material, but excluding narcotics or scheduled substances).
Restricted matter	Biosecurity matter which is not permitted matter or prohibited matter. Defined in s.21 of the *Biosecurity Act 2019* (Tas)
Risk Group	A system of classification of microorganisms according to the degree of risk. Defined in s.3.2 of AS2243.3.
Security Sensitive Biological Agent (SSBA)	Security Sensitive Biological Agent. SSBAs are high-risk biological agents which have the potential to cause significant damage to human health, the environment and the Australian economy. At present, there are no facilities at the University which may store or use SSBAs.
TBIRD	Tasmanian Biosecurity Import Requirements Database.
TSD	The OGTR's Transport, Storage and Disposal guidelines.
Toxin	A small, poisonous molecule produced by a biological agent.
University	All references to the University relate to the University of Tasmania.
WHO	World Health Organisation

Legislation

The two key Commonwealth instruments relating to this framework are:

- the *Biosecurity Act 2015,* which provides for managing biosecurity risks and emergencies, specifically concerning the risk of exotic pests or infectious diseases entering Australia, becoming established or spreading, and;
- the *Gene Technology Act 2000*, which aims to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

These instruments sit at the top level of the legislative environment surrounding biosecurity and gene technology, as shown in Figure 1.

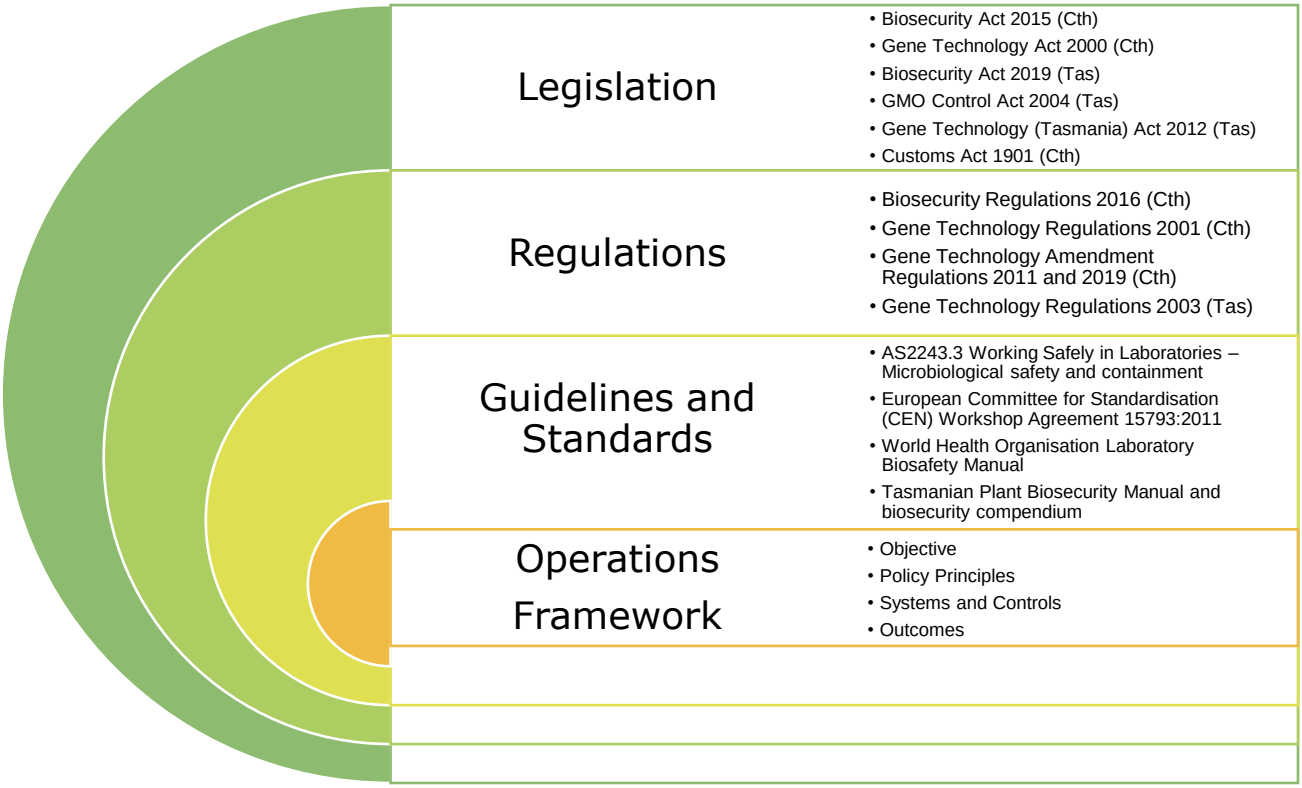

Figure 1: The biosafety, biosecurity and gene technology legislative environment. This framework adopts a management system approach to identify, understand and address risks.

Tasmanian legislation also provides for the management of biosecurity and gene technology at the state level. The *Biosecurity Act 2019* (Tas) was assented in 2019 and replaces seven previous acts relating to plant and animal biosecurity.

An amendment to the *Genetically Modified Organisms Control Act 2004* (Tas) was also assented in 2019, and provides for a ten-year extension to Tasmania's moratorium on the release of GMOs to the environment. This impacts the potential for the University of Tasmania to apply for DIR licences from the OGTR in the state, as intentional release of GMOs is currently prohibited.

While not directly related to gene technology or biosafety, the *Customs Act 1901* relates to biosecurity in regard to certain provisions for the import of goods from outside Australia.

Regulations

The *Biosecurity Act 2015* and *Gene Technology Act 2000* are supported by comprehensive regulations (the *Biosecurity Regulations 2016* and *Gene Technology Regulations 2001* respectively) which describe requirements for effective risk management and penalties for non-compliance.

Regulations to accompany the *Biosecurity Act 2019* (Tas) are yet to be developed, although it is anticipated that this will occur in 2020, along with the creation of a biosecurity compendium – an online resource detailing requirements for importing a variety of risk materials to Tasmania. The *GMO Control Act 2004* (Tas) enforces the *Gene Technology Regulations 2001* for conducting dealings with GMOs in Tasmania.

Biosecurity Regulations 2016

To manage the risks to the Australian and Tasmanian economy, the natural environment and society from pests and diseases entering, establishing or spreading, the *Biosecurity Regulations 2016* outline restrictions to the import of certain goods to Australian Territories. In general terms, the regulations restrict or conditionally prohibit the import of risk materials by stipulating conditions for the inspection, treatment and/or containment of these materials in a facility approved by the Department of Agriculture (an Approved Arrangement). The potential risk of imported materials is established through evidence-based assessments known as a Biosecurity Import Risk Analyses (BIRA), which are conducted by the Department of Agriculture. The chain of custody of risk materials must be documented, and compliance with conditions is audited by the Department at least once per year.

Gene Technology Regulations 2001

The *Gene Technology Regulations 2001* outline restrictions for certain dealings with GMOs and gene technology via an accreditation and licencing system. It adopts a co-regulatory model whereby accredited organisations must have access to an Institutional Biosafety Committee which can provide approval for low risk dealings to be conducted in containment facilities. Higher risk dealings, and those involving intentional release to the environment, require direct scrutiny by the regulator.

Guidelines and Standards

Australian biosecurity and gene technology regulations are underpinned by guidelines and standards, which provide a descriptive, outcome-focussed system for managing risks associated with biological agents.

Compliance with Australian Standard 2243.3 *Safety in Laboratories – Microbiological Safety and Containment* ("AS2243.3") is enforced by both the *Biosecurity Regulations 2016* and the *Gene Technology Regulations 2001*, and provides an outline of requirements for construction and operation of containment facilities. It also categorises microbiological agents into risk groups based on their individual and community risk. Compliance with this standard is a condition for the issue of import permits and other approvals relating to gene technology and imported biological materials.

The CEN Workshop Agreement (CWA) 15793:2011 – *Laboratory Biorisk Management*, developed by the European Committee for Standardisation, is a management system for controlling risk to human health from microbiological agents. The CWA is under consideration for upgrade to an ISO standard in 2020, and is widely recognised as defining international best practices for biorisk management.

The World Health Organisation Biosafety Manual (3rd ed.) provides information and fundamental concepts to encourage the development of management systems and codes of practice for handling pathogenic microorganisms in laboratories. The manual complements AS2243.3 and is a useful reference which may be used to guide the implementation of systems and controls within the framework.

The Tasmanian Plant Biosecurity Manual gives practical expression to current Tasmanian biosecurity legislation, and assist businesses and the general public to comply with Tasmanian law. It is prescriptive, and specifies the measures required to fulfil legislative requirements. It is anticipated that the Plant Biosecurity Manual will be replaced by a biosecurity compendium once updated regulations are in place.

This framework draws on these guidelines and standards to recommend a systematic approach to biosafety, biosecurity and gene technology risk control, and identify where responsibility lies for management of risks. It applies to activities conducted at the University of Tasmania which are governed by the overarching legislation and regulations listed.

Framework Outline and Objective

The framework is built on a hierarchical pyramid of controls broken up into:

- a high-level objective;
- foundation policy principles;
- systems and controls recommended to fulfil policy principles, and
- desired outcomes to demonstrate success.

Figure 2 describes the pyramid of controls.

The pyramid is capped by the objective to define and implement best-practices for identifying, understanding and addressing risks to human health, primary production and the natural environment arising from the use of gene technology, biologically-hazardous materials and imported materials at the University of Tasmania. The objective provides an overarching vision to define relevant policy principles and systems to deliver the outcome goals.

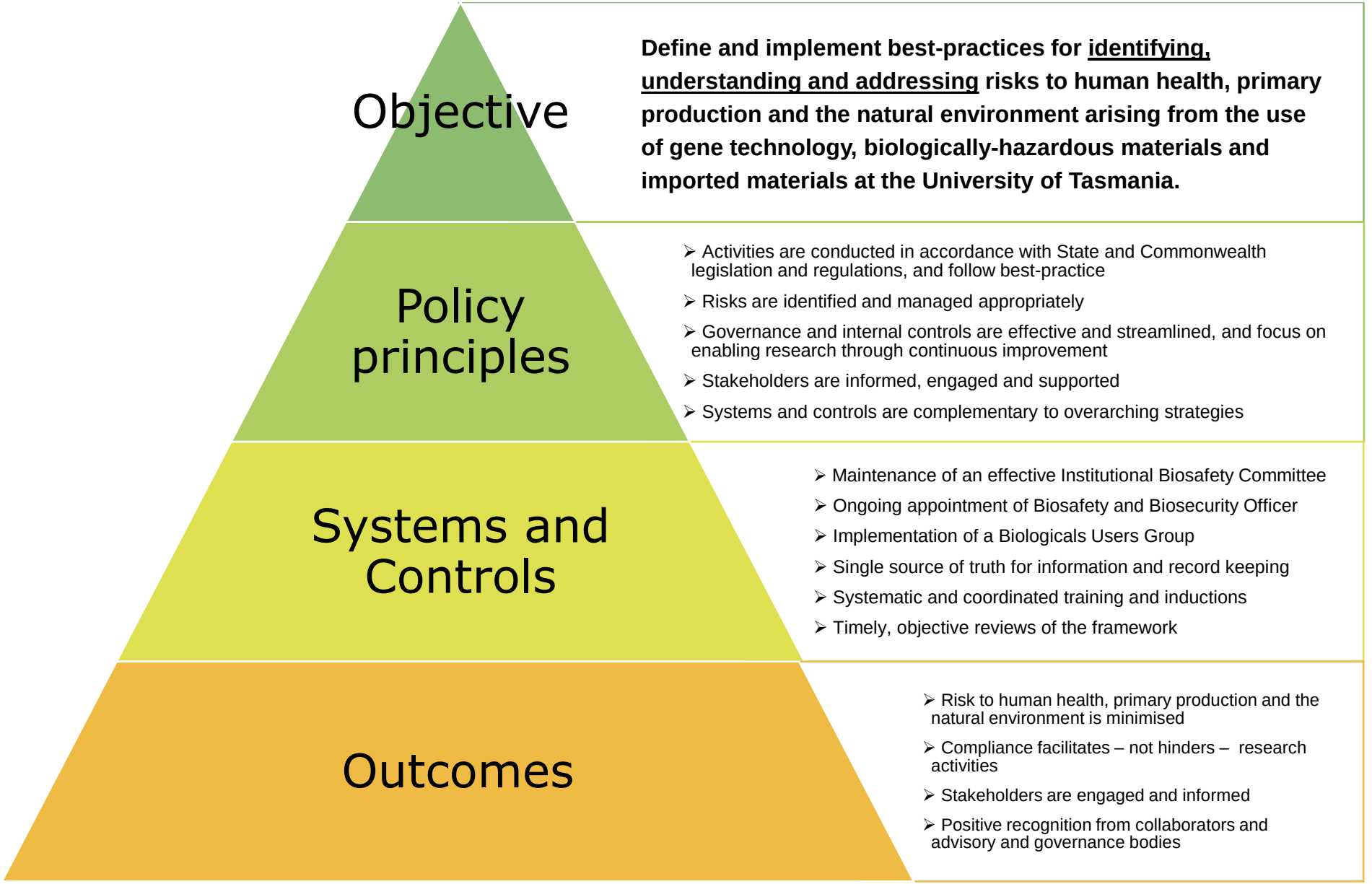

Figure 2: Framework Pyramid of Controls

Policy Principles

The framework lists five policy principles. These policy principles are descriptive and should be used to direct decision-making and operations to deliver the objective. They aim to complement the strategic direction of the University, and work in harmony with strategies of Colleges and Institutes. The policy principles are as follows:

1. Activities are conducted in accordance with State and Commonwealth legislation and regulations, and follow best practice

The University has a range of legal obligations, and through the *Legal Compliance Framework*, ensures that it observes and complies with all statutory laws and regulations. The University must also provide demonstration to governance bodies that obligations are met and/or managed effectively. This policy principle complements the *Legal Compliance Framework* and promotes the documented use of best practices, such as Australian and international standards, to guide activities and conduct research in accordance with regulations.

2. Risks are identified and managed appropriately

Risks involved with gene technology, biologically-hazardous materials and imported materials may adversely affect human health, primary production and the natural environment, but also cause legal or reputational risk to the University from non-compliance or adopting substandard practices. It is crucial that all relevant risks are identified, assessed and managed appropriately to facilitate safe research activities at the University. Management of these risks is a shared responsibility – University management must provide a policy statement to recognise the special hazards associated with gene technology, biologically-hazardous materials and imported materials; workers must implement the principles of risk assessment prior to commencement of dealings to demonstrate that hazards are controlled.

3. Governance and internal controls are effective and streamlined, and focus on enabling research through continuous improvement

For the framework to be implemented successfully, suitable governance mechanisms and internal controls must be implemented. In line with the University's strategic direction, it is appropriate for these to be guided by the value they add to stakeholders, and avoid unnecessary administrative duplication or red tape. Internal controls must enable – not inhibit – research activities to achieve the objective.

4. Stakeholders are informed, engaged and supported

Stakeholders, most importantly:

- Researchers and HDR students working with gene technology, biologically-hazardous materials and imported materials, and
- Facility Managers overseeing workplaces where this research is conducted,

are central to the adoption of the framework, and require accurate information and timely support. By ensuring their engagement, the importance of compliance, risk management and best practices can be disseminated to the broader University community, and the University's commitment to best practices can be demonstrated to potential collaborators.

5. Systems and controls are complementary to overarching strategies

The development and implementation of strategic plans at the University, College, Institute and Division levels provide context in which the framework must operate. Ensuring that systems and controls are complementary to overarching strategic initiatives aims to remove duplication of efforts and facilitate framework acceptance and uptake.

Systems and Controls

The systems and controls section of the framework provides recommendations for actions required to deliver the objective. These are split into six priority areas, and are guided by the policy principles. In line with the principal of continuous improvement, it is anticipated that implementation of the controls listed below will be completed. New systems, controls and actions will emerge to address regulatory changes, new research areas, developing risks and technological advances.

1. Maintenance of an effective Institutional Biosafety Committee

The Institutional Biosafety Committee (IBC) is the authoritative body at the University regarding dealings involving the *Gene Technology Act 2000*, and is established in accordance with the guidelines issued by the OGTR under section 98 of the Act. The Committee is made up of invited University staff and external representatives.

The IBC should:

- Assess proposed low-risk dealings with genetically modified organisms to be conducted by the University and other accredited organisations as appropriate;
- Monitor national and international guidelines and standards to define and recommend best practices;
- Take a broad and proactive role in advising how activities involving gene technology, biologically-hazardous materials and imported materials are used at the University, including implementation and maintenance of risk assessment resources;
- Maintain a reporting line to Research Division management;
- Provide high-level regulatory advice to University management as required, and
- Facilitate the implementation of University-wide procedures and guidelines regarding legislative compliance and best practice.

The terms of reference for the IBC were rewritten in 2018 to implement this control, and will be reviewed annually to ensure they remain fit for purpose.

2. *Ongoing appointment of a Biosafety and Biosecurity Officer*

A provision of AS2243.3 is that a Biological Safety Officer shall be contactable to provide advice and guidance on microbiological safety. While the responsibilities of the Biological Safety Officer are not prescribed, the University's Biosafety and Biosecurity Officer is the most appropriate person to provide relevant advice and guidance.

The Biosafety and Biosecurity Officer should:

- Take ownership of the framework and champion the policy principles amongst stakeholders;
- Provide advice to stakeholders when planning research activities to assess and minimise risks;
- Advise or participate in reporting, investigation and follow-up on non-compliance events;
- Ensure that relevant and current information is available to stakeholders, and
- Contribute to the development and delivery of training activities.

To achieve these recommendations, the Biosafety and Biosecurity Officer should have a sufficient level of delegation to administer relevant activities, and be allocated sufficient time and resources to perform their job effectively. The Biosafety and Biosecurity Officer should be independent from a College, and have direct access to University management when necessary.

The Biosafety and Biosecurity Officer position was made ongoing in 2019 to implement this control.

3. *Implementation of a Biologicals Users Group*

Consultation and communication are key parts of an effective management system. Maintaining a user group of empowered stakeholders provides an opportunity for disseminating information, training opportunities and consultation activities in a coordinated and documented way.

The Biological Users Group should:

- Have no barriers to membership, nor be compulsory;
- Establish the notion that risk and compliance management regarding biosafety, biosecurity and gene technology is a distributed – not centralised – responsibility;
- Include representation from the IBC to provide the means to escalate risk-related concerns;
- Share experiences and resources, and provide a forum to discuss operational requirements, safe working procedures, risk management controls and regulatory updates;
- Avoid a 'blame culture', and provide members with a friendly environment to discuss operational best practices and approaches to improve work safety;
- Provide opportunities to stakeholders to extend their skills and knowledge to enhance the collective understanding of risks, regulatory requirements and obligations, and
- Be consulted and have involvement in reviews of the framework and updates to recommendations.

A biological users group was launched in 2019 to implement this control.

4. *Single source of truth for information and record keeping*

It is imperative that stakeholders are supported with accurate, timely and relevant information relating to risks, regulations and obligations. To minimise confusion and duplication, a single source of truth for this information should be provided. It is recommended that this be achieved through webpages hosted centrally within the Research Division website.

Regulatory requirements require accurate and comprehensive recordkeeping to be undertaken by accredited organisations. This is best achieved using digital tools, and should include the maintenance of:

- An electronic management system for tracking GMOs, imported materials and biologically-hazardous materials;
- A repository of assessment records for dealings approved by the IBC;
- Internal and external audit reports, non-compliances and auditor recommendations;
- A comprehensive list of facilities where relevant activities may be undertaken.

A suite of new webpages and a repository of IBC assessment records was launched in 2019 to commence implementation of this control.

To further support a lean approach to record keeping and managing compliance obligations, minimising the number of DAWE Import Permits issued to the University is recommended. It is anticipated that this will be achieved between 2020-2022 as current permits expire and can be replaced.

5. Systematic training and inductions

To identify risks and manage them appropriately, requirements and procedures for training staff, students and visitors must be established, maintained and updated regularly. To minimise duplication of effort and maximise value for stakeholders, training resources should be coordinated across Colleges, and should address:

- How training needs for staff and students are established and provided;
- How risks from imported biological material, gene technology and biological agents are defined and controlled;
- How effective implementation of training is measured;
- Means to restrict access to facilities and materials to ensure activities are not conducted by staff and students who are not trained, and
- Provisions for appropriately maintaining training records.

Documented risk assessment resources and behavioural obligations are also recommended, and may be achieved via the publication of a University Biosafety Manual, which may be annexed within operations manuals of each relevant facility.

Information resources should:

- Be publicly accessible (ie. not on an intranet page or behind a secure login) to display the University's commitment to following best practice;
- Be updated regularly;

- Be written in plain English and include contemporary definitions of key terms, and
- Be reviewed during routine facility audits.

6. Timely, objective reviews of the framework

It is critical that the framework is reviewed at timely intervals, at least annually, to ensure it remains fit-for-purpose, effective and reflective of prevailing regulations and emerging technology. Framework reviews should:

- Be consultative, and incorporate feedback via the biologicals users group and relevant stakeholders;
- Assess opportunities for improvement in the context of aiming to address risks, deliver value for stakeholders and maintenance of adequate resourcing, and
- Include information sourced from facility audits, non-compliance events, status of risk assessment activities, follow-up actions from previous reviews and results of incident investigations.

Outcomes and Indicators of Success

The framework lists four outcomes which are anticipated to result from the implementation of the systems and controls. These outcomes are:

- Risk to human health, primary production and the natural environment is minimised;
- Compliance facilitates – not hinders – research activities;
- Stakeholders are engaged and informed, and
- Positive recognition from collaborators and advisory and governance bodies.

These outcomes represent positive benefits arising from the implementation of the framework, and represent the result of achieving the framework objective.

The following indicators may be used to establish whether the outcomes have been achieved:

Leading Indicators

- Timely submission of applications for import permits and avoidance of a 'just-in-time' culture towards obtaining permits and approvals to conduct research;
- Strong and/or increasing uptake of training opportunities;
- Growing membership of biologicals users group;
- Increased volume of enquiries directed to Biosafety and Biosecurity Officer;
- Increased number of Exempt Dealing and NLRD applications submitted to IBC, and
- Consolidation of import permit applications into broad institutional permits, and an increased number of requests to access institutional permits.

Lagging Indicators

- Stakeholder satisfaction expressed during consultation opportunities;
- Facility compliance audit pass rate approaching 100%;
- Reduction in non-compliance events to negligible levels;
- Higher quality of applications submitted to IBC;
- Past performance, e.g. stakeholder satisfaction, audit success, better quality of NLRD applications;
- Timely achievement of annual deliverables listed in IBC Terms of Reference, and
- Increase in containment facility utilisation.

Scope

While broad in nature, and applicable to areas outside biosafety, biosecurity and gene technology, the framework seeks to define systems to control the risks associated with the acquisition, use and disposal of material under biosecurity control, genetically modified organisms, microbiological agents and toxins at the University.

In scope	Out of scope
- All research activities (and the University facilities in which they are conducted) which involve: ○ Material under biosecurity control, including the import of risk material to Tasmania or Australia; ○ Genetically modified organisms (as defined by the *Gene Technology Regulations 2001*), gene technology and synthetic biology; ○ Microorganisms and toxins classified into risk groups 1-4 (AS2243.3).	- Security sensitive biological agents (SSBAs) - Hazardous chemicals and dangerous goods - Activities occurring at partner organisations - Agreements between the University and state government (e.g. response to biosecurity emergencies by TIA staff) - National management plans for animal movement, pest and disease control, and surveillance - Farm and wildlife biosecurity - Policy and procedure related to: ○ Public health; ○ Clinical trials; ○ Animal welfare; ○ Scheduled drugs and poisons (including narcotics, medicinal cannabis and opium poppies).

Accountabilities and Responsibilities

To realise the outcomes of the framework, responsibility for systems and controls must be taken by stakeholders. The table below divides responsibilities amongst stakeholders in line with the University's *Regulated and Hazardous Biological Materials Policy*.

Role	Responsibility
University management	- Maintain institutional accreditation from the OGTR under sections 91-98 of the *Gene Technology Act 2000*. - Sustain the resources and procedures necessary to enable effective oversight of dealings. This includes resourcing and convening an IBC. - Hold appropriate facility certifications to conduct activities with Regulated Biological Materials. This includes Approved Arrangements, Physical Containment certifications and Approved Quarantine Places. - Employ a Biological Safety Officer (the "Biosafety and Biosecurity Officer") as defined under Section 1.5.10 of AS2243.3. - Employ or nominate a staff member (the "Facility Manager") to be accountable for each facility where dealings are performed. - Maintain a register of all current gene technology Exempt Dealings, NLRDs and Licensed Dealings conducted by the University and assessed by the IBC. - Provide access to training and continuing education to members of the IBC on relevant legislation and developing topics relating to biosafety, biosecurity and gene technology. - Ensure that facilities provided to staff and students conducting dealings are constructed and/or furnished to a standard which meets regulated containment requirements appropriate to the dealings.
Institutional Biosafety Committee	- Comply with the conditions of accreditation as set out in the instrument of accreditation issued by the OGTR. - Assess and monitor dealings to ensure they are conducted in accordance with legislation, regulations, Australian Standards, codes of practice, University policies and licencing requirements. This includes reviewing risk assessments where appropriate, and ensuring staff and students conducting the research are adequately experienced and qualified. - Inspect, or facilitate inspections of, all certified University facilities annually and keep records of these inspections. - Provide guidance and training to Facility Managers, staff and students when completing applications for relevant permits, licences, authorisations and certifications for Dealings. - Develop, implement and maintain usage procedures, guidelines and training materials relating to gene technology and GMOs, imported materials and biologically-hazardous materials. - Notify relevant authorities promptly of the occurrence or suspected occurrence of Biosecurity Events or breaches of legislative or regulatory compliance by the University.
Biosafety and Biosecurity Officer	- Act as the primary contact between the University and relevant governing or advisory bodies (including the OGTR, DAWE, Biosecurity Tasmania and ABSANZ). - Manage the University's Biosecurity Industry Participant account with DAWE, including facilitating submission of import permit applications, compliance agreements and facility certification applications. - Act as the IBC secretariat and provide strategic and operational support to the committee via *Ex Officio* membership.

	- Maintain effective communication with the University's ethics committees to provide advice on issues pertaining to biosafety, biosecurity and gene technology. - Maintain information resources for staff and students relating to biosafety, biosecurity and gene technology. This includes assisting the IBC with development and implementation of user groups, procedures, guidelines and training materials. - Prepare and disseminate Annual Reports to the OGTR, the University Research Committee (URC), and official communiques to relevant authorities as required. - Guide and assist Facility Managers to rectify any Corrective Action Requests or non-conformances issued by regulatory authorities. - Endeavour to demonstrate good corporate citizenship by regularly submitting abstracts to relevant professional fora, and volunteering on ABSANZ governance committees. - Fill the role of Biological Safety Officer as defined in AS2243.3.
Facility Managers	- Provide training and induction to users of their facility and ensure training materials are reviewed and updated regularly. - Manage and maintain their facility/facilities to ensure regulated containment requirements appropriate for the dealings conducted within the facility are implemented. - Report any issues including breaches of containment, non-compliances, or condition which renders their facility unsuitable for use to the IBC and Biosafety and Biosecurity Officer immediately. - Follow direction and guidance issued by the Biosafety and Biosecurity Officer to rectify any Corrective Action Requests or non-conformances issued by regulatory authorities in a timely manner. - Maintain a working knowledge of guidelines, regulations and policies relating to activities occurring in their facility with assistance from the Biosafety and Biosecurity Officer. - Facilitate effective communication between academics responsible for research activities and staff and students conducting dealings within their facility. - Review risk assessments completed by staff and students conducting dealings within their facility to ensure hazards are controlled.
Staff and Students	- Obtain approval from the IBC, DAWE, Biosecurity Tasmania or any other relevant regulatory body as required prior to conducting any dealings with GMOs, gene technology, imported material or biologically-hazardous material. - Complete a risk assessment meeting the guidelines of Section 2.1.2 of AS2243.3 prior to conducting any dealings. Dealings may only be undertaken after the risk assessment has been approved by the Facility Manager or the IBC. - Seek guidance from the IBC, Biologicals Users Group or Biosafety and Biosecurity Officer on any matters relating to biosafety, biosecurity or gene technology where necessary. - Ensure they are adequately trained and qualified to undertake the activities related to any dealing they intend to conduct.

	- Comply with any related University policy, including the *Legislative Compliance Policy*, procedure or guideline, and any direction or condition of any certification, licence, agreement or permit issued to them. This includes reporting the occurrence or suspected occurrence of biosecurity events or breaches of legislative or regulatory compliance that they may become aware of to the IBC, Biosafety and Biosecurity Officer and Facility Manager promptly. - Conduct dealings only within appropriate facilities. - Follow any direction or condition issued by the IBC, Biosafety and Biosecurity Officer or relevant Facility Manager. - Submit annual reports to the IBC regarding facilities, NLRDs and licence compliance regarding any relevant dealings undertaken or proposed.

Risk Management

The following risks have been identified in relation to development and implementation of the framework.

Risk	Consequences	Risk Rating	Mitigations	Residual Risk Rating
Lack of commitment by top management	*Inadequate resourcing; lack of prioritisation; poor integration of framework systems throughout the organisation; recurrence of issues is not prevented*	*High*	- *Maintain direct communication and rapport between Biosafety and Biosecurity Officer, IBC Chair, DVCR, Executive Director (Research Operations) and Research Integrity and Ethics Manager* - *Biosafety and Biosecurity Officer acts as framework champion to promote the adoption of recommendations and systems* - *Maintain focus on continual improvement and update framework regularly* - *Provision of appropriate training to stakeholders to reinforce the importance of risk management and promote resources for improvement* - *Inform Research Division management of successes and non-compliances*	*Moderate*
Stakeholder buy-in is poor and/or there is resistance to implement framework	*Outputs are not fit for purpose; framework is not accepted or is complex and unclear*	*High*	- *Undertake extensive consultation* - *Promote framework to university management and obtain support prior to implementation* - *Biosafety and Biosecurity Officer acts as framework champion to promote the adoption of recommendations and systems* - *Adequate delegations appointed to Biosafety and Biosecurity Officer*	*Moderate*

Controls are not developed and implemented	*Framework not implemented fully; non-compliance with regulations or legislation*	*High*	- *Supporting materials developed in consultation with stakeholders* - *Plan a timeline for development and implementation of controls* - *Identify opportunities for improvement and prevention, determine the root cause of issues and prevent reoccurrence*	*Low*
Framework design is not fit for purpose	*Framework or controls do not address regulations; information resources incorrect*	*High*	- *Undertake extensive consultation with stakeholders* - *Regularly review and update framework* - *Benchmark against other universities and maintain rapport with national biosafety, biosecurity and gene technology communities* - *Thoroughly review legislation and regulations* - *Be proactive in communications and consultative opportunities presented by regulators* - *Representation at OGTR forums and ABSANZ annual conferences* - *Biosafety and Biosecurity Officer maintains membership of ABSANZ Regulatory Liaison Committee* - *Implement guidance provided in CWA 15973:2011*	*Low*
Resources are insufficient	*Outputs not realised; engagement from regulators is lost*	*Moderate*	- *Ongoing appointment of Biosafety and Biosecurity Officer* - *Chair of IBC is remunerated* - *Provision of resources to deliver training resources and engage with stakeholders* - *IBC is resourced to function appropriately and independently and to provide representation at national fora and conferences* - *Framework controls become priority activities for Biosafety and Biosecurity Officer* - *Regular dialogue with Research Division management to ensure framework implementation is prioritised*	*Low*

Appendix 1: Stakeholder List

The following stakeholders have been identified as relevant to the implementation of the framework.

Inform	• University Research Committee • Deputy Vice-Chancellor Research • Associate Deans Research, College of Health and Medicine and College of Sciences and Engineering • Executive Director, Research Operations
Consult	• Institutional Biosafety Committee • Animal Services • Central Science Laboratory • WHS Manager • Chairs of Animal and Human Ethics Committees • Heads of Schools and Institutes • HDR students under the direction of owners of regulated biological materials • Manager – Compliance • Legal Services • Members of ABSANZ and governance sub-committees • External auditors
Involve	• IBC Chair • Facility Managers of certified/approved facilities • Manager, Research Integrity and Ethics Unit • Owners and users of regulated biological materials

Appendix 2: Relevant Legislation and Regulations

Title	Description	Regulator
Gene Technology Act 2000 (Cth)	Identifying risks posed by, or as a result of gene technology, and managing those risks through regulating certain dealings with GMOs	Gene Technology Regulator (OGTR)
Gene Technology Regulations 2001 (Cth)	The licencing system for dealings with GMOs	Gene Technology Regulator (OGTR)
Gene Technology Amendment Regulations 2011 and 2019 (Cth)	Updates to the Gene Technology Regulations	Gene Technology Regulator (OGTR)
Gene Technology (Licence Charges) Act 2000 (Cth)	Liability for charges to hold GMO dealing licences	Gene Technology Regulator (OGTR)
Gene Technology (Tasmania) Act 2012 (Tas)	Applies commonwealth gene technology acts as a law of Tasmania	Biosecurity Tasmania
Genetically Modified Organisms Control Act 2004 (Tas)	Provisions to implement a moratorium on the commercial release of GMOs in Tasmania	Biosecurity Tasmania
Biosecurity Act 2015 (Cth)	Provide for managing biosecurity risks to Australia	Department of Agriculture
Biosecurity Act 2019 (Tas)	Provide a regulatory framework for Tasmanian biosecurity risk management	Biosecurity Tasmania
Biosecurity Regulations 2016 (Cth)	System for controlling biosecurity risk material and approval of containment facilities	Department of Agriculture
Customs Act 1901 (Cth)	Administration of tariffs and duties relating to imported goods	Australian Border Force

Appendix 3: Relevant Standards and Guidelines

Title	Description
AS2243.3 *Safety in Laboratories – Microbiological Safety and Containment*	Australian Standard describing requirements for microbiological safety in laboratories and containment principles
CWA 15793 *Laboratory Biorisk Management*	European CEN Workshop agreement describing a management system for controlling risks associated with biological hazards
OGTR Guidelines for Accreditation of Organisations	Requirements for obtaining an instrument of accreditation from the OGTR to conduct dealings with GMOs
OGTR Guidelines for the Certification of Physical Containment Facilities	Requirements for certification of containment facilities where authorised dealings with GMOs may occur
OGTR Guidelines for the Transport, Storage and Disposal of GMOs	Requirements for dealings involving transport, storage and disposal of GMOs
WHO Laboratory Biosafety Manual	Guidelines for microbiological safety in laboratories
Plant Biosecurity Manual Tasmania	Outline of current requirements for import and export of plants, plant products and other prescribed material into and out of Tasmania