Biosafety - Importing and Exporting Biological Material Procedure

Section 1 - Summary

(1) This Procedure:

a. outlines Victoria University's (VU) processes for importing biological material (including live animals) into Victoria and Australia. It is intended to provide guidelines to promote biosafety and prevent unintended spread of microorganisms, pest animals and plants.
b. outlines VU processes for exporting biological material out of Australia;
c. ensures compliance with biosafety legislation, regulations and standards that VU must follow.

(2) Australia has strict biosecurity measures for the import and export of biological material. The Australian Government publishes information about import conditions and permits through the biosecurity import conditions database (BICON). BICON lists the import conditions for thousands of goods.

Section 2 - HESF/ASQA/ESOS Alignment

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

Section 3 - Scope

(4) This Procedure applies to all VU staff that need to import or export biological material, and Technical staff and Managers that maintain laboratories where biological material is used.

Section 4 - Definitions

(5) BICON – BICON is the Department of Agriculture's biosecurity import conditions system. Allows clients to obtain import conditions for specific commodities without having to contact the department.

(6) Certificate of origin – A certificate of origin states the country of origin of the goods. The seller, manufacturer or a chamber of commerce in the country of origin may issue certificates of origin.

(7) Defence and Strategic Goods List 2021 (Cth) – The DSGL is a legislative instrument for the purposes of the Legislation Act 2003. The purpose of the DSGL is to list goods and technologies subject to export control and provides guidance to multiple agencies. The DSGL underpins Australia's export controls and is required to ensure that Australia remains compliant with its international obligations.

(8) Export – A consignment is considered to be exported either:

a. when it is lodged with the freight forwarder, shipping company/airline, charter operator or an appointed agent

in the country of origin, for ultimate destination in Australia

b. when it is shipped on board the vessel
c. when it is packed in a container and sealed in preparation for export.

(9) Freight forwarder – A person or corporation who arranges transport of goods on behalf of either the seller or buyer. A freight forwarder will often consolidate several small shipments into one larger shipment to take advantage of better freight rates. In most cases, the freight forwarder will assume the legal liabilities of acting as a carrier.

(10) IATA – The International Air Transport Association (IATA) supports aviation with global standards for airline safety, security, efficiency and sustainability.

(11) Importer – For the purposes of this procedure, the importer is the person or company importing the goods.

(12) Import permit – Some products have been assessed as posing a significant risk to Australia Biosecurity and are only allowed to be imported if the Department of Agriculture, Fisheries and Forestry grants an import permit. VU has one permit, which is managed by the Biosafety Manager.

(13) Material Transfer Agreement (MTA) – A Material Transfer Agreement (MTA) is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives.

(14) Security Sensitive Biological Agents (SSBA) and Standards – The SSBA Standards are determined under section 35 of the National Health Security Regulations 2018. They set out the requirements that must be met by the entity to ensure physical security around handling, storage, disposal, and transport of SSBAs and biological agents suspected of being SSBAs, as well as personnel and information security.

(15) Waybill – A document prepared by the carrier of a shipment of goods that contains details of the shipment, route and charges.

Section 5 - Policy/Regulation

(16) Biosafety Policy

Section 6 - Procedures

Part A - Summary of Roles and Responsibilities

Roles	Responsibilities
Deputy Vice-Chancellor, Research & Impact (DVC-RI)	Responsible to the Vice-Chancellor for VU's Institutional Biosafety Committee (IBC) and its implementation of requirements as specified by regulatory bodies in relation to the handling of Biological Risk Group Agents.
Executive Director, Research Services	Responsible to the DVC-RI to ensure that the Senior Manager, Research Infrastructure and Biosafety, advises and reports on the regulatory and legislative requirements the handling of Biological Risk Group Agents, and is adequately supported to develop, implement, monitor and review associated procedures and guidelines.
Senior Manager, Research Infrastructure and Biosafety	Authorised to advise on and report to the IBC on legislative requirements for the handling of Biological Risk Group Agents.

Roles	Responsibilities
Directors, Executive Deans and Heads of Department	Responsible for ensuring that all staff and students receive appropriate information and training necessary for them to handle Biological Risk Group Agents in accordance with all legislative requirements.
Manager, Technical Services	Responsible for ensuring that designated research spaces are adequately supported so that Biological Risk Group Agents can be handled in a compliant and safe manner. Ensure that Technical Managers have resources to develop and implement training and procedures necessary to ensure that all handling of Biological Risk Group Agents is in accordance with all legislative requirements.
Technical Managers	Ensure that all end-users of Biocontainment facilities are adequately trained and competent, and that there are procedures in place to ensure that all Biological Risk Group Agents are handled in accordance with regulatory and legislative requirements.
Project Supervisor / Subject Coordinator (including Principal/Chief Investigators, 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 the handling of Biological Risk Group Agents.
Staff, Students, Volunteers and External Users of University Facilities	Ensure that they follow safety guidelines and abide by VU's Procedures for handling of Biological Risk Group Agents, as set out by VU and their respective Technical Manager and Project Supervisor/ Subject Coordinator. Ensure that their actions do not put themselves, or any other individual at risk.
Senior Officer, Animal Ethics and Biosafety	Acts as the IBC Secretary and as such is responsible for receiving and sending communications between Project Supervisor / Subject, Coordinator, End-Users, Facility Managers / Supervisors and the IBC.

Part B - Permits and Licensing Requirements

(17) VU Staff must use the University's BICON Import Permit to import controlled biological material as outlined in this Procedure.

(18) VU Staff must not import:

a. goods from countries from the sanctioned countries list.
b. goods prohibited by Customs (which includes those listed on the Defence and Strategic Goods List 2021 (Cth) (DSGL)), as additional restrictions and licensing is required. Contact the Senior Manager, Research Infrastructure and Biosafety for further information.
c. goods classified as Security Sensitive Biological Agents (SSBA), detailed on the SSBA List, as additional licensing is required. Contact the Senior Manager, Research Infrastructure and Biosafety for further information.
d. plants and animals classified as prohibited, controlled, or regulated pests, as additional restrictions and licensing is required. Contact the Senior Manager, Research Infrastructure and Biosafety for further information.

Part C - Authorised Use of the University Biological Import Permit

(19) The Senior Manager, Research Infrastructure and Biosafety is the only person authorized to apply for biological import permits at VU and will maintain a register or authorised biological import permits.

(20) Biological import permits are administered by the Technical Staff responsible for the laboratories where the goods will be used.

(21) Biological import permits must not be obtained by the End-user.

(22) End-users will confirm whether they require an import permit by determining the commodity classification of their goods using the Biosecurity Import Conditions on the BICON website. If uncertain about the classification of goods, the End-user must contact the Senior Manager, Research Infrastructure and Biosafety.

(23) The VU Biological Import Commodity List should be consulted before importing any commodities. For items that are not on the list, please consult the Senior Manager, Research Infrastructure and Biosafety.

How to apply for authorised use of University Biological Import Permit

(24) End-Users should first consult the How to Import Biological Material Flowchart.

(25) To request the use of a permit, the End-User must complete the online Request to Import Biological Material Form. This form must be completed by End-Users that intend to receive ANY biological material that the University needs to import from overseas. This includes biological material that will be received through the mail, via international couriers or custom agents.

(26) The form should be accompanied by the Suppliers Declaration Letter sample template.

(27) It is the End-Users responsibility to confirm the classification of their commodity and sign the declaration agreeing to abide by the conditions of the permit.

(28) The completed form must be submitted by email to the Senior Manager, Research Infrastructure and Biosafety for review and authorised approval to import the material if acceptable.

(29) Following approval, the VU import permit will be issued to the VU Technical Manager responsible for the laboratories where the goods will be stored and used.

Part D - Approval of new Biological Import Permits

(30) Importation of biological material not listed on the VU BICON permit may require a new import permit.

(31) If a new permit is required, the End-User should complete the Request to Import Biological Material Form.

(32) The Senior Manager, Research Infrastructure and Biosafety will apply for the permit on behalf of the University.

(33) Once BICON approves the permit, the Senior Manager, Research Infrastructure and Biosafety will authorise the VU Technical Managers to administer the permit, as required, to the End-Users.

(34) Depending on the goods, it can take BICON up to 20 working days to assess the permit.

(35) Fees may be charged to an account specified by the End-User if the goods are assessed as project specific.

Part E - BICON Permit Conditions for Importation of Biological Material

(36) The BICON conditions under which the permit is granted are written on the permit. These include but are not limited to:

a. Administrative conditions
    i. Quarantine entry document, invoice, waybill or importers manifest may be required.
b. Entry conditions
    i. Restriction to quantities and/or sizes of containers may apply.

ii. Forced irradiation of goods may apply.
iii. Restrictions on countries of origin may apply.

c. Packaging and Labelling Conditions
   i. Goods must be packaged to comply with all the relevant governing bodies. For a list of governing bodies, see the Biosafety Website.
   ii. To ensure compliance with packaging requirements the End-user must also consult the following IBC resources which details the regulatory requirements that must be met by the Biosafety - Packaging and Transport of Biological Materials Procedure.

d. Post entry/end-use conditions
   i. Restriction to use in vitro, in vivo in laboratory animals and/or in vivo in humans may apply.
   ii. Restriction to Laboratory certification requirements may apply.
   iii. Restrictions to the transfer of goods to third parties may apply.

(37) The End-user must ensure the entry; packaging and post-entry conditions on the permit are met at all times. Fees may be charged to an account specified by the End-User if the goods are assessed as project-specific.

(38) Once received, the End-User should refer to the Biosafety - Packaging and Transport of Biological Materials Procedure.

Part F - Export of Biological Materials

(39) An OHS risk assessment must be completed for export goods and sent to the Technical Manager for review before they are handled.

(40) Where applicable, project-specific approval must have been granted (i.e: IBC, AEC and/or VUHREC).

(41) Staff will check if there is a need to obtain a permit to export goods. Consult the Department of Agriculture, Fisheries and Forestry (DAFF) for further information.

(42) Staff must check the country of interest specific importing requirements.

(43) Staff must not export goods to countries on the sanctioned countries list.

(44) Goods must be packaged as outlined in the mode of transport and relevant dangerous goods code. For air transport, a certified packer must pack goods.

Part G - Legislative Requirements

(45) It is important that Staff understand and ensure they adhere to the VU procedure for importing and exporting any biological material.

(46) If authorised material is brought into Australia without the relevant import permit, the material will be confiscated and destroyed by Biosecurity and Custom’s officials and the End-User liable for potential prosecution.

(47) The Biosecurity Act 2015 (Cth) states that conditionally non-prohibited goods must not be brought or imported into Australian territory unless the specified conditions (including conditions for administrative purposes) are complied with.

(48) It is a criminal offence, pursuant to section 186 of the Act, to bring or import goods into Australian territory without an import, where one is required.

(49) The Act does not provide for permits to be issued after the goods have been brought into Australian territory.

Status and Details

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