Biosafety - Import, Export, Transport and Packaging of Biological Material Procedure

Section 1 - Purpose / Objectives

(1) This document outlines the Victoria University (VU) procedure 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 and pest animals and plants.

(2) This procedure is required to ensure compliance with biosafety legislation, regulations and standards that VU must follow.

(3) Australia has strict biosecurity measures for the import and export of biological material. Infectious materials are classified as Class 6 Dangerous goods. The transport of Class 6 Dangerous Goods is subject to a number of State, National and International legislation. An up to date list of legislative requirements can be obtained on the Biosafety Website.

Section 2 - Scope / Application

(4) This procedure applies to:

a. All VU personnel that need to import, export, transport or package biological material.
b. All Professional Services Technicians that maintain laboratories where biological material is used.

Section 3 - Definitions

(5) Nil

Section 4 - Policy Statement

(6) See Biosafety Policy.

Section 5 - Procedures

Roles/Responsibilities

(7) Key responsibilities and accountabilities are outlined in the Biosafety Governance Procedure (pending).

Procedures

A. Permits & licensing requirements

(8) VU personnel must use the University's Biological Import Permit to import controlled biological material as outlined

in this procedure.

(9) VU personnel must not import goods from countries on the sanctioned countries list (see: VU Quality and Compliance - Sanctions Compliance website).

(10) VU personnel must not import goods prohibited by Customs (which includes goods listed on the Defence and Strategic Goods List), as additional restrictions and licensing is required. Contact the Manager, Research Infrastructure and Biosafety for further information.

(11) VU personnel must not import goods classified as Security Sensitive Biological Agents (SSBAs) as additional restrictions and licensing is required. Contact the Manager, Research Infrastructure and Biosafety for further information.

(12) VU personnel must not import plants and animals classified as prohibited, controlled, or regulated pests as additional restrictions and licensing is required. Contact the Manager, Research Infrastructure and Biosafety for further information.

B. Use of the University Biological Import Permits

(13) The Biosafety Manger is the only person authorized to apply for biological import permits at VU.

(14) The Biosafety Manger will maintain a register of biological import permits at VU.

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

(16) Biological import permits are administered by the Technicians responsible for the laboratories where the goods will be used.

(17) The University will maintain import permits for commonly used biologicals.

a. A list of commodities that can be imported is available on the Biosafety Website (see: VU Biological Import Permit Commodity List)
b. Permits for commodities not listed on the VU Biological Import Permit Commodity List will be provided on a needs basis (see Section C).

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

(19) To use a permit the End-user must complete the Request to Import Biological Material Form and sign the declaration agreeing to abide by the conditions of the permit.

a. This form must be completed by personnel 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.
b. It is the End-user responsibility to confirm the classification of their commodity.
c. This form must be submitted to Manager, Research Infrastructure and Biosafety for review and then the Laboratory Technical Manager for processing.

(20) - Once approved, the Laboratory Technical Manager will supply the permit to the End-user.

C. Approval of new Biological Import Permits

(21) Importation of biological material not listed on the VU Biological Import Permit Commodity List must be approved

by the Manager, Research Infrastructure and Biosafety.

(22) If a permit is required, the End-user must complete the Request to Import Biological Material Form .

(23) The completed form must be emailed to the Manager, Research Infrastructure and Biosafety.

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

a. The fees may be charged to an account specified by the End-user if the goods are assessed as project-specific.
b. Depending on the goods it can take the government up to 90 working days to assess the permit.

(25) Once the government approves the permit the Manager, Research Infrastructure and Biosafety will authorize the Laboratory Technical Managers to supply the permit as required to the End-users.

D. Conditions of Importation of Biological Material

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

a. Administrative conditions e.g.
    i. Quarantine entry document, invoice, waybill or importers manifest may be required
b. Entry conditions e.g.:
    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 e.g.:
    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 is encouraged to consult the following IBC resources:

    (27) Packaging and labelling requirements for the import of biological material - Laboratory Safety Guideline

    (28) Supplier's Declaration Letter - Sample template

    (29) How to Import Biological Materials - Flow chart

d. Post entry/end-use conditions e.g.:
    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.

(30) The End-user must ensure the entry; packaging and post-entry conditions on the permit are met at all times.

E. Other Conditions

(31) In addition to the import requirements, End-users may be required to comply with other governing bodies e.g.:

a. For importation of Genetically Modified Organisms - the End-user must have a valid IBC project.
b. For importation of human therapeutics for human use - the End-user must have a valid human ethics project, see the Victoria University Human Research Ethics Committee website.

c. For importation of animals, the End-user must have a valid animal ethics project & follow the animal ethics committee (AEC) guidelines & SOPs when transporting and handling animals, see the AEC website.

(32) It is the End-users responsibility to ensure they are compliant with all relevant governing bodies at all times.

F. Receiving, Recording and Unpacking Biological Material

(33) The End-user must records goods on the local laboratory biological inventory register. For guidelines to preparing inventories see: Biological Risk Group Agent Sample Inventory Table.

G. Facilities

(34) End-user must ensure that they have access to the appropriately certified laboratory to work in and permission from the College and Laboratory Manager that runs the facility to use it.
There are currently no Quarantine Approved Premises (QAPs) at VU. Examples of biological products that may require QAP include: highly pathogenic/exotic microorganisms; samples for laboratory analysis (food, water, soil etc.); and agricultural products requiring further processing. To establish a QAP contact the Manager, Research Infrastructure and Biosafety.

H. Renewal of Permits

(35) Import permits expire every two years and will be renewed by the Manager, Research Infrastructure and Biosafety as required.

I. Releasing impounded/seized goods

(36) End-users must read the conditions of the permit carefully. Failure to comply may result in confiscation of goods, goods requiring treatment, or fines. Non-compliance is also punishable under the Criminal Code of Australia.
If goods are impounded, please contact the Manager, Research Infrastructure and Biosafety immediately.

J. Taxes & Duties

(37) The End-user must contact VU Financial Services to ensure all duty & taxes are paid.

K. Material Transfer Agreement (MTA)

(38) A Material Transfer Agreement (MTA) may be required when importing goods from some supplier's.
If in doubt, the End-user must contact the College's Research Facilitation and Development Manager to discuss requirements for a MTA and to get MTA's approved.

L. Training

(39) Personnel intending on importing and exporting material must complete the online "Compliance with the regulations for import, export and transport of biological material" course (IBC-T003#) available via the Biosafety Website.
Personnel that package goods for international transport must be a certified IATA packer.

M. Biological Approved lists

(40) Only goods that are listed on the VU Biological Agents Approved Lists can be used at VU. If the biological is not listed, please complete the Biological Risk Agent Notification Form and submit this to the Manager, Research Infrastructure and Biosafety before importing any goods.

N. Risk Assessments

(41) Importation of biological material may have safety implications. It is an Occupation Health and Safety (OHS)

requirement that a Risk Assessment using the OHS Risk Assessment Form is conducted and approved before the acquisition of any goods. Please contact the OHS team for further information.

Section 6 - Guidelines

(42) IBC LSG 013 Laboratory Safety Guideline - Packaging and labelling requirements for the import of biological material

Section 7 - Templates

(43) Nil

Section 8 - Supporting Documents

(44) A copy of the legislation can be downloaded from the VU Governance & Secretariat Website.
All supporting documents can be found on the Biosafety Website by contacting the Manager, Research Infrastructure and Biosafety (ibc@vu.edu.au).
The following Procedures have been referenced in this document:

a. IBC P002 Internal Certification of Containment Facilities Procedure
b. IBC P003 Dealings Involving Genetically Modified Organisms Procedure
c. IBC P004 Import, Export, Transport & Packaging of Biological Material Procedure
d. IBC P005 Non-Compliance and Adverse Incidents Procedure
e. IBC P006 Biosafety Governance Procedure

(45) The following Forms have been referenced in this document:

a. IBC F004 Biological Risk Agent Notification Form
b. IBC F005 Biohazard Material Project Application Form
c. IBC F006 Incident Form
d. IBC F009 Request to Import Biological Material Form

(46) The following Documents have been referenced in this procedure

a. IBC D001 Supplier's Declaration letter - Sample Template
b. IBC D002 How to import Biological material - Flow Chart
c. IBC D003 Biological Permit Commodity List
d. IBC D004 Biological Risk Agent Inventory Table
e. IBC D008 - D010 VU Biological Agents Approved Lists

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