Biological Risk Management and Containment

Importation of Restricted Biologicals

Import and Transfer

Containment Laboratory Guidelines

Version 2.1- October 2024

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Record of Amendments to Version 2.1

Date	Page number	Nature of amendment
30/9/2024	15	Update BACC example to new format
30/9/2024	20	Edit to new declaration format
30/9/2024		Minor edits throughout document
30/11/24	8	Sentence deleted about scitrack
30/11/24	9	Type of label added in point 9
30/11/24	20	Appendix 3 information updated
30/11/24	all	University logo updated

Contents

1. Who are these guidelines for?

These guidelines are for **principal investigators (PIs), designated persons in charge, designated laboratory person (DLPs)**, technical staff and students wanting to import **restricted biological materials** or genetically modified organisms (GMOs).

2. What is the purpose of these guidelines?

The supply chain for items qualifying as imported restricted goods is complex and may involve people who do not understand New Zealand import requirements. The purpose of this document is to help users understand and manage the importation of risk biologicals, meet post-entry quarantine requirements and obtain the required documentation.

3. What is the process for importing biological material?

When biological material is imported into New Zealand it must be accompanied by a valid Permit to Import unless the item is considered to be a biological product of negligible risk. Where the item is a **restricted/risk biological** or a **GMO,** it will be directed to a transitional or containment facility for quarantine.

The main reasons for the quarantine of imported restricted biological products, cell lines and GMOs in a transitional or containment facility is to minimise the risk that any organism will:

- Cause unwanted harm to natural and physical resources or human health in New Zealand
- Interfere with the diagnosis, management or treatment, in New Zealand, of pests or unwanted organisms

University containment and transitional facilities must, therefore, be able to account for all imported restricted materials, including their initial importation, their movement to University facilities and their subsequent storage, use and disposal. To this end, systems are in place to ensure the correct use of Permits to Import, the proper receipt and storage of biological materials and their documentation in the laboratory.

There is a **central register** of uncleared biological goods imported into each containment facility. Each individual laboratory also uses **SciTrack** to maintain a record of uncleared biological goods in use, in storage and disposed of.

4. How to obtain import permits

Send requests for import to the designated person in charge. This person will not issue the Permit to Import until sufficient information is supplied for them to determine which permit to issue.

The designated person in charge issues it to the requester as a pdf, *with the appropriate descriptor highlighted, and the date and central register number stamped on it, so that the permit can only be used once, and only for the item requested.* The Permit to Import is to include instructions for import and receipt. For details on different applicable permits, please refer to Appendix 2.

The designated person in charge is to maintain a database of requests for use of Permits to Import along with details of items, the name of requestor, the laboratory group/PI and the issued permits. This data is then reconciled with the **Biosecurity Authority Clearance Certificate** (BACC) related to the import. Soft copies of BACCs are to be stored.

The BACC number and Central Register Number are to be entered into the SciTrack register by the designated laboratory person (DLP). SciTrack therefore serves as both lab inventory and central register for imported risk goods.

5. How to purchase products that require an import permit

1) The researcher is to make the request for purchase in SciTrack, and after consulting with the DLP and provisionally selecting the correct permit, send an import permit request form via email to the designated person in charge, formally requesting a permit.
2) The DLP is to process the purchasing request in SciTrack only when the researcher has obtained the correct permit. The DLP is then to forward the request and the relevant permit to STC.
3) The **hazard approver** may only approve the purchase once satisfied that the correct permit has been issued.
4) The purchase order and permit are then to be forwarded to the overseas vendor by STC.

5) In most cases MPI will send an electronic BACC to the designated person in charge. BACCs are occasionally attached to the package.
6) If the item arrives without a BACC, the DLP *is to request a BACC number from the designated person in charge.*
7) If a BACC has not been sent either electronically or as hardcopy, the designated person in charge is to request a retrospective BACC from MPI.
8) The designated person in charge then sends a declaration to the DLP (see Appendix 3, page 17).
9) The DLP is to store the restricted goods appropriately and enter all details into SciTrack (including the BACC# and Central Register Number)
10) The DLP is to send a copy of the completed declaration (with accurate description of goods, the BACC# and the SciTrack barcode number) to the designated person in charge.
11) On receipt of the declaration, the designated person in charge is to enter the SciTrack barcode number into the central register.

6. How to request products that require an import permit but no purchase order

1) The researcher is to ~~make the request for purchase in SciTrack, and after consulting~~ consult with the DLP as to whether a product requires an import permit. They should provisionally select the correct permit and send an import permit request via email to the designated person in charge, formally requesting a permit.
2) Once the DLP receives the electronic copy of the permit, it is to be forwarded to the overseas supplier, along with instructions for importation.
3) Repeat 5-10 above

7. How to obtain correct BACCs

MPI identifies risk goods at the NZ border, and provided the correct permit has been supplied, will direct these goods to a containment/transitional facility. MPI issues this direction order via a BACC.

MPI sends BACCs pertaining to restricted biologicals (i.e. those for which a restricted permit has been issued) to containment@auckland.ac.nz

The designated person in charge who receives the restricted BACC is to determine whether or not:

- All the relevant information is correct
- The item(s) have been received at the correct containment or transitional facility

Where a restricted BACC has not been issued or the BACC has incorrect information, the designated person in charge is to apply for a retrospective BACC. A record of each application for a retrospective BACC is to be kept on the central register. BACCs are generally not sent for unrestricted biologicals (i.e. issued under a general permit), as the material is cleared at the border and not subject to a direction order.

The importing laboratory is to ensure the correct BACC is obtained and also to query what might be an incorrect importation. In the case of an incorrect BACC, the imported item is to be embargoed until the correct BACC is obtained.

The designated person in charge is to log restricted imports in the central register, , for tracking and audit purposes. A soft copy of the BACC should also be saved. The designated person in charge is also to note retrospective BACCs in the importation log.

Laboratories are not required to file copies of BACCs but may request them. The recipient receives a declaration from the DLP confirming exact details of imported goods along with the central register number and the SciTrack barcode number. A copy of the declaration is shown in Appendix 3.

8. Unpacking imported restricted biological products, microorganisms and cell cultures

Whenever an uncleared biological product, microorganism or cell culture is imported into a containment or transitional unit, the DLP who unpacks the goods is to check that:

- The integrity of the package has been maintained
- The package has been delivered to the right place and person
- All appropriate documentation has been included and is in order
- Primary and secondary packaging is intact and there is no leakage
- Numbers and descriptions correlate with accompanying documentation
- The identity of the item is correct and there are no additional items

- The packaging material is disposed of appropriately

The DLP is to forward all paperwork to the designated person in charge immediately shipment is received. This will enable the faculty to apply for any retrospective permits if the usual notifications fail.

If the package is leaking, incorrect items have been sent, or the documentation is missing/ incorrect, notify the designated person in charge immediately.

9. Storage

All imported or transferred risk goods are to be stored in cabinets, refrigerators or freezers labelled as containing Biological Hazards. The purpose of the label is to warn other users of the presence of restricted goods.

Where imported goods are stored in a fridge or freezer, the risk goods are to be stored in a marked container such as a larger plastic box. This is to ensure all risk goods are in a single place and that laboratory personnel return them to a single nominated container within the cupboard, fridge or freezer.

10. Keeping laboratory records

Laboratories are required to keep a laboratory register of imported risk goods within SciTrack. Items are to be recorded as whole containers, or if it is a kit comprising multiple containers, the number of containers is to be recorded.

SciTrack records are to include

- An accurate description of the item(s)
- The date of importation
- The BACC number for restricted imports
- The central register numbers
- The SciTrack barcode number
- The exact storage location
- Timely information about consumption and/or destruction

Laboratory records are to be kept for seven years.

11. Transferring restricted imported materials

Any transfer of restricted imports out of a containment or transitional facility requires prior MPI approval, following the procedure set out in the guidelines *Transfer of Restricted Biologicals*.

If the material is transferred to another laboratory in the containment facility, the receiving lab is to keep a record in SciTrack of:

- The storage location in the laboratory
- Date of disposal, if applicable
- MPI approval for any transfer to another containment facility or re-export

12. Verification

Verification that the processes described above are providing adequate management of imported goods consists of two quantitative measures:

1) A three-monthly comparison of University records with MPI records that shows not more than 5% deviation
2) An internal audit that accounts for all restricted goods at laboratory level

Key performance indicators (KPIs) are as follows:

1) Deviation between MPI and University records as a percentage of imports
2) Number of retrospective BACCs as a percentage of total imports for a given period

12.1 Three -monthly comparison of University and MPI importation records

Where MPI records do not show an import or BACC, MPI is to be informed. Where an import or BACC is missing, immediate corrective action is to be taken to obtain a copy of the BACC from MPI in order to track the item to the laboratory. The aim is to locate the item, update the databases and ensure correct storage.

Greater than 5% deviation demonstrates that the above processes need to be reviewed.

Comparisons are to be recorded on the form specified in Appendix 4.

13. Definitions

BACC means Biosecurity Authority Clearance Certificate (also known as the cargo number). **Restricted BACCs** are BACCs related to restricted goods, which serve as a direction order from MPI. A representative BACC is shown in Appendix 1.

Central register means an electronic register of all transfers and restricted imports, showing details of item and vendor as well as BACC number and MPI approval number, enabling this information to be cross-referenced with documentation stored on SciTrack.

A **Genetically Modified Organism (GMO)** is an organism modified by in vitro manipulation for which approval to import or to develop is required under the Hazardous Substances and New Organism (HSNO) Act. GMOs must be held in a Ministry of Primary Industries-approved containment facility as a primary control condition of HSNO approval. Movement of GMOs from a containment facility requires prior specific approval under the HSNO Act.

General Permit to Import means permit used for imports of biological material that is considered to be of negligible biosecurity risk, and hence is not required to be held in a transitional facility. Staff are not required to record the use and disposal of unrestricted biological imports.

Restricted biological imports means biological materials (such as serum, animal tissue, Genetically Modified Organisms or cell lines) that have been imported under a restricted Permit to Import and directed to be held in a New Zealand Ministry of Primary Industries approved transitional or containment facility under the Biosecurity Act. Under the Biosecurity Act, movement of restricted biological imports from a containment or transitional facility requires specific prior approval.

Restricted Permit to Import means those Permits to Import whose post-entry conditions require the imported material to be held in a New Zealand Ministry of Primary Industries approved transitional or containment facility. Under the Biosecurity Act, movement of restricted biological imports from a containment or transitional facility requires specific prior approval.

SciTrack register means an electronic register of all GMOs and restricted imports, showing details of host vector and insert as well as BACC number and exact location.

Unrestricted biological imports mean imports of biological material that is considered to be of negligible biosecurity risk, and hence is not required to be held in a transitional facility. Staff are not required to record the use and disposal of unrestricted biological imports.

Designated laboratory person (DLP) means the trained person in each research group who has been given the authority to approve purchase requests made in SciTrack and to make a formal request for a purchase order via PeopleSoft. In containment and transitional facilities DLPs will have additional training to enable them to scrutinise documentation for restricted items and provide support to researchers.

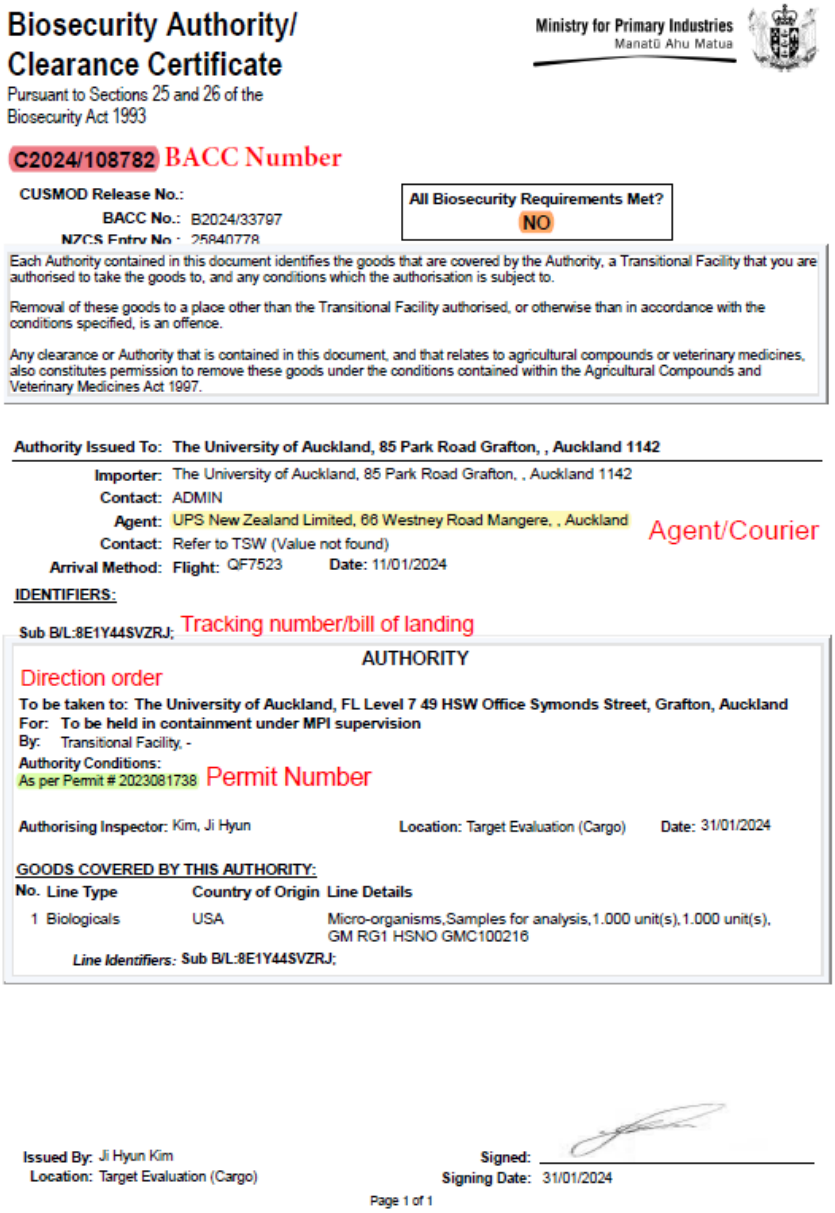
Designated person in charge means a staff member in any of the following roles: sector manager, facility manager, floor manager, technical manager, technical team leader or an appointed delegate.

Hazard approver (HA) means the trained persons in each faculty who have been given the authority to approve the purchase of restricted and controlled items in PeopleSoft.

Operator is the person legally authorised by the Ministry of Primary Industries to be responsible for the management of a registered containment facility. For the purposes of these guidelines, the operator may appoint a delegate.

Principal Investigator (PI): In the context of hazard containment and transitional facilities, a principal investigator is the holder of an independent grant administered by the University and the lead researcher for the grant project, usually in the sciences, such as a laboratory study or a clinical trial. The phrase is also often used as a synonym for "head of the laboratory" or "research group leader." The PI is responsible for assuring compliance with applicable University standards and procedures, and for the oversight of the research study and the informed consent process. Although the PI may delegate tasks, they retain responsibility for the conduct of the study.

14. Appendix 1: BACC



Biosecurity Authority/ Clearance Certificate

Pursuant to Sections 25 and 26 of the Biosecurity Act 1993

Ministry for Primary Industries
Manatū Ahu Matua

C2024/108782 BACC Number

CUSMOD Release No.:
BACC No.: B2024/33797
NZCS Entry No.: 25840778

All Biosecurity Requirements Met? NO

Each Authority contained in this document identifies the goods that are covered by the Authority, a Transitional Facility that you are authorised to take the goods to, and any conditions which the authorisation is subject to.

Removal of these goods to a place other than the Transitional Facility authorised, or otherwise than in accordance with the conditions specified, is an offence.

Any clearance or Authority that is contained in this document, and that relates to agricultural compounds or veterinary medicines, also constitutes permission to remove these goods under the conditions contained within the Agricultural Compounds and Veterinary Medicines Act 1997.

Authority Issued To: **The University of Auckland, 85 Park Road Grafton, , Auckland 1142**

Importer: The University of Auckland, 85 Park Road Grafton, , Auckland 1142
Contact: ADMIN
Agent: UPS New Zealand Limited, 66 Westney Road Mangere, , Auckland
Contact: Refer to TSW (Value not found)
Arrival Method: **Flight:** QF7523 **Date:** 11/01/2024

Agent/Courier

IDENTIFIERS:

Sub B/L:8E1Y44SVZRJ; Tracking number/bill of landing

AUTHORITY

Direction order

To be taken to: **The University of Auckland, FL Level 7 49 HSW Office Symonds Street, Grafton, Auckland**
For: **To be held in containment under MPI supervision**
By: Transitional Facility, -
Authority Conditions:
As per Permit # 2023081738 Permit Number

Authorising Inspector: Kim, Ji Hyun **Location:** Target Evaluation (Cargo) **Date:** 31/01/2024

GOODS COVERED BY THIS AUTHORITY:

No.	Line Type	Country of Origin	Line Details
1	Biologicals	USA	Micro-organisms,Samples for analysis,1.000 unit(s),1.000 unit(s), GM RG1 HSNO GMC100216

Line Identifiers: Sub B/L:8E1Y44SVZRJ;

Issued By: Ji Hyun Kim
Location: Target Evaluation (Cargo)

Signed: _____
Signing Date: 31/01/2024

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15.Appendix 2: Introduction to the importation of biological material

15.1 MPI Import Permits

Regardless of the biological material to be imported, it must be authorised by MPI Import Management. This authorisation is the Permit to Import Biological Products (i.e. MPI Import Permit)

There are four import permits for University of Auckland - a General Permit, two Restricted Transitional Permits and a Restricted Containment Permit.

15.2 General permits

A general permit has no conditions attached and hence the item is cleared at the border - provided it meets the description on the permit.

15.3 Restricted permits

A restricted permit is for items with perceived higher risk and has conditions attached. The most common condition imposed on such permits is that the items must go directly to a containment facility (if it is a restricted biological or a GMO). Therefore, such items are not cleared at the airport.

There are three restricted permits: Restricted Biologicals (nonviable) Import Permit, Restricted Biologicals (viable) Import Permit and GMO Import Permit.

There is an exception to the permit system for human cells (see below).

Items on restricted permits cannot be uplifted from the airport but must go directly to the transitional or containment facility. MPI will allow a courier to transport the item(s) to the containment facility. If the item is not being shipped "door-to-door" by a courier company, you are to pre-arrange a courier to take the items from the airport to the containment facility,or obtain a letter from the **operator** indicating you are taking this material directly to the containment facility.

Once in the containment facility, you are to retain documentation pertaining to the item's importation, its location in the laboratory and an account of disposal.

All items being imported into containment must stay in the facility and prior MPI approval is to be obtained for transfer or re-export.

15.4 Non-GM human cell lines:

The importation of non-GM human cell lines is not regulated under the Biosecurity Act. However, these cell lines are shipped in media that contains imported foetal calf serum and bovine-derived supplements. In most instances, human cell lines can be imported as non-restricted if accompanied by a manufacturer's declaration that confirms the reagent is commercially manufactured and packaged, has been treated so as to render any viable microorgansisms non-viable, is for laboratory use only and is not intended for use in the production of products destined for use in or on animals as veterinary medicines, and either not derived from blood or serum, or if it is, it is highly purified and/or sterilised.

Non-GM human cell lines are then entered into SciTrack as a restricted cell line.

15.5 Requirements for importation on a restricted permit for GMOs

15.5.1 Importation using a courier (recommended method)

1) Attach a copy of the current MPI Import Permit (with descriptor highlighted). Make sure you have the correct permit.
2) Ensure that your name and contact details are clearly documented on the parcel and that you include either FMHS or SBS in the address.
3) If the consignment is large with multiple vials, you must also have an inventory of the items in the consignment.

15..5.2 Importation as passenger luggage (least preferred option, and must be authorised by the signatory in charge of issuing permits)

Ensure you have the following:

1) A copy of the restricted permit with the descriptor highlighted
2) A letter from the **operator** (or delegated designated person in charge) indicating you are authorised to use the permit and that the items will be taken directly to the containment facility from the airport (MPI will not allow the importer to take the item from the airport to the facility)

3) If the consignment is large with multiple vials, you must also have an inventory of the items in the consignment.
4) A copy of the EPA approval (with relevant section highlighted)

Note: you may not bring GMOs into New Zealand in passenger luggage.

15.6 Packaging

Please make sure the consigner packs the items strictly in accordance with IATA 650 Packing Instructions.

- Packaging must consist of three components.
- The primary receptacle(s) must be leak-proof and must not contain more than 1L; (NB: A screw-capped receptacle is required)
- The secondary packaging must be leakproof.
- There must be absorbent material placed between the primary receptacle and the secondary packaging; if several fragile primary receptacles are placed together in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them. The absorbent material, such as cotton wool, must be in sufficient quantity to absorb the entire contents of the primary receptacles ~~and there must be a secondary packaging which must be leak-proof.~~
- The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing an internal pressure differential of not less than 95kPa in the range of –40°C to 55°C (-40°F to 130°F). (See note above about using a screw capped receptacle).
- The outer packaging must not have a capacity greater than four litres.

15.7 After importation

Forward all paperwork to the designated person in charge immediately the shipment is received. This will enable the faculty to apply for any retrospective permits if the usual notifications fail.

While records of each import are kept centrally, the receiving lab is to also keep the following records in SciTrack:

- The date and description of all the items imported

- The storage location in your laboratory (both the storage box and the refrigerator/freezer must be clearly labelled as containing imported material)
- Record of any disposal (contact the designated person in charge)
- MPI approval for any transfer to another containment facility or re-export (contact the designated person in charge)
- The date that any material is transferred to another lab in the containment facility

If the material is transferred to another lab in the containment facility, the receiving lab is to keep a SciTrack record of:

- The storage location in your laboratory
- Record of any disposal
- MPI approval for any transfer to another containment facility or re-export

These items are to be kept in a secure area, i.e. *an area where only authorised people have access and where there is some form of access control*.

16. Appendix 3: Declaration

Item description provided:

Supplier:

Central register number:

BACC number:

HSNO organism approval number (if required):

Item description: [Recipient to provide an accurate description with number of vials etc.]

SciTrack barcode number: [Recipient to provide SciTrack barcode number]

Declaration:

I have read and understood the requirements for storage and documentation of imported or transferred GMOs and risk goods.

In particular:

- I understand that all restricted imports are to be entered into SciTrack along with a record of the BACC number and the **Central Register Number**.
- I understand that I must enter any necessary details on restricted organisms when required (including HSNO organism approval code, species, relevant modification).
- I understand that restricted imports are to be kept in clearly labelled containers within clearly labelled fridges or freezers.
- I understand that I must be able to locate the restricted import easily.
- I understand that I must store these items only in a containment laboratory.
- I understand that I am to obtain MPI approval for any subsequent transfer or export of imported risk goods or GMOs.
- I agree to follow these procedures and seek further clarification if I do not understand.

Name:

Date:

17. Appendix 4: Comparison of MPI and University import records

Date:	
Period covered:	
Auditor:	
Facility	
Number of MPI items listed	
Number of University items missing from MPI records	
Percentage	
Explanation:	
Number of MPI items missing from University records	
Explanations	