Standard Operating Procedure

Task/Activity/Equipment: Transport of GMO and pathogenic biological goods subject to IATA Dangerous Goods Regulations by road, rail, and air	
Purpose: To outline the requirements and conditions applying to the transport of GMOs, infectious microorganisms, and samples containing these when such goods are transported by air, road, rail, or water.	
Location: Various locations – intrastate, interstate and overseas	**Reference Number:** IBC-SOP-28 **Version:** 2.0
Written by: Dr Jess Hall, Biosafety Specialist	**Reviewed by:** Institutional Biosafety Committee
Approved by: Belinda Cox, Biosafety Officer	
IBC approval date: May 2023	**Revision required date:** May 2028
Replaces the version: IBC-SOP-15 and IBC-SOP-16, Version 1	
Changes to the last approved version: Consolidation of Category A, B and C Dangerous Goods Requirements into single SOP.	

1. POTENTIAL HAZARDS

Infectious substances	Liquid nitrogen
Risk group 1 or 2 microorganisms	Carbon dioxide (dry ice)
Genetically modified organisms	
Diagnostic specimens	

2. TERMS & ACRONYMS

CASA	Civil Aviation Safety Authority
DG/DGC	Dangerous Goods / Dangerous Goods Class
DSGL	Defence Strategic Goods List
GM/GMO	Genetically Modified / Genetically Modified Organism
IATA	International Air Transportation Association
UN	United Nations
WHS	Work Health and Safety

3. RELEVANT LEGISLATION, GUIDELINES & STANDARDS

- *IATA Dangerous Goods Regulations* [current version]
- AS 4834 '*Packaging for surface transport of biological material that may cause disease in humans, animals, and plants'*
- Australia Post *Dangerous and Prohibited Goods Packaging Guide*
- *Australian Code for the Transport of Dangerous Goods by Road and Rail*
- The International Maritime Organisation *International Maritime Dangerous Goods Code*
- United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations

Unless otherwise specified, the IATA *Dangerous Goods Regulations* are the primary legislative instrument, and in general, incorporate the requirements of the other regulations. Collectively, the regulations define requirements for certification, packaging instructions, labelling, maximum quantities, and Shipper's Declaration requirements.

Note that the *IATA Dangerous Goods Regulations* are updated annually. The most recent copy must be consulted for current requirements.

4. SWP SCOPE AND COVERAGE

This document is for use by University researchers who need to transport Category A, B, infectious biological samples, Category C or exempt non-infectious biological materials, or Class 9 Miscellaneous Dangerous Goods in the form of GMOs, however, is not intended to cover the following sample types:

- items requiring biosecurity containment (as defined under the *Biosecurity Act 2015*).
- risk group 3 or 4 microorganisms (as defined under *AS/NZS 2243.3*); or
- live animals.

The procedures outline Australian requirements for transporting biological material considered to present a biological hazard, including infectious, and diagnostic material transported by air or surface. These procedures assist researchers in ensuring that they are compliant with legislative requirements when transporting infectious or potentially infectious biological materials, GMOs, and exempt specimens.

The transport of biological material is regulated under a variety of legislation. The legislation to be followed depends on whether transport will be by air, post, road, or rail, and whether the biological materials are infectious, genetically modified, or biosecurity-affected materials.

The intent of all transport regulations is that packaged material should not escape from the package under normal conditions of transport.

5. CATEGORISATION OF BIOLOGICAL MATERIAL FOR TRANSPORT

Samples which are known or reasonably expected to contain pathogens are **Class 6.2 Dangerous Goods**. Pathogens are defined as microorganisms (including, but not limited to, bacteria, viruses, parasites, fungi) and other agents such as prions that can cause disease in humans, animals, or plants. Examples of Class 6.2 samples include biological products, cultures, patient specimens, and medical or clinical waste.

Category A & B

1. **Category A** – an infectious substance which is transported in a form that, when exposure to it occurs, can cause permanent disability, life threatening or fatal disease to humans, animals, or plants.

   Note: An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans, animals, or plants (environment).

   An indicative (but non-exhaustive) list of Category A microorganisms is provided in the United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations *and in AS 4384 (*accessible on campus via SAI Global: https://www.saiglobal.com/online/autologin.asp*)*.

2. **Category B** – infectious material that does not meet the criteria for inclusion in Category A and is known or suspected of containing less virulent pathogens (e.g., risk group 2 pathogens, as defined in AS/NZS 2243.3).

Category C & Exempt

3. **Category C** – defined in AS 4384 and applicable only within Australia for surface transport only (i.e., road or rail). Includes biological material with a low probability of causing disease in humans, animals, or plants. This covers human, animal or plant samples including excreta, secreta, blood and its components, tissues and tissue fluids, and cell cultures not belonging to Category A or B biological material.

4. **Exempt** – defined in the IATA *Dangerous Goods Regulations* and applicable internationally for samples transported by surface or air. Includes samples where there is minimal likelihood that pathogens are present – e.g., a urine sample being sent for diagnostic testing.

The following substances meet the requirements for Category C or Exempt materials (unless they contain other substances (e.g., chemicals) that meet the criteria for inclusion in another class):

- Substances that do not contain infectious substances, or substances that are unlikely to cause disease in humans, animals, or plants.

- Substances containing microorganisms that are non-pathogenic to humans, animals, or plants.
- Substances in a form where any present pathogens have been neutralised or inactivated such that they no longer pose a health risk.
- Environmental samples (including food and water samples) that are not considered to pose a significant risk of infection.
- Dried blood spots (collected by applying a drop onto absorbent material).
- Specimens from humans or animals with non-infectious diseases (minimal likelihood that pathogens are present).

Category C and Exempt category substances are not considered to be Dangerous Goods; however, these samples still need to meet packaging and labelling requirements specified in this document.

UN Numbers for biological material

The international regulations for transport of infectious substances, diagnostic specimens, and GMOs by any mode of transport are based on the recommendations of the United Nations (UN) Committee of Experts on the Transport of Dangerous Goods.

Most dangerous goods have a UN number assigned to them - for biological materials, the most common are:

- Infectious Substances affecting humans – UN 2814
- Infectious Substances affecting animals only – UN 2900
- Diagnostic specimens & Category B – UN 3373
- GMOs (non-toxic & non-infectious) – UN 3245
- Carbon dioxide (dry ice) – UN 1845

For a full list of UN dangerous goods numbers, see: http://adrdangerousgoods.com/eng/substances/all/

6. TRANSPORT REQUIREMENTS – GENERAL PRINCIPLE

In general, assume that transport of biological materials to an overseas destination will involve transport by air. In cases where multiple modes of transport apply (e.g., road transport of materials to an airport, for further shipment via air), the most stringent transport, packaging and labelling conditions of those different transport modes will apply – typically this will be the requirements for transport by air.

7. TRANSPORT BY AIR

Category A & B Goods

Category A & B biological materials are not permitted on commercial flights carrying passengers or crew (other than pilots) and can be sent via cargo aircraft only. This must be arranged with a commercial courier company.

You are not permitted to pack Category A and B biological material for transport by air unless you have done a CASA approved training course. This certification must be renewed every 2 years. At Flinders University, contact the Biosafety Officer (ibcadmin@flinders.edu.au) if you require assistance with packaging these goods – ensure plenty of prior notice is given, and that you have obtained required packaging materials and labels.

The alternative is to pay trained commercial couriers (such as World Courier or Labcabs) to pack and deliver your material for you.

Category C & Exempt

Although Category C and Exempt materials are not classified as Dangerous Goods, the regulations say that an element of professional judgment is required to determine if a substance meets these categories. For this reason, the regulations specify that secure packaging is still required, with reduced labelling requirements. A

consignment note/ airway bill is required for such shipments. See Packaging and Labelling sections for further details of these requirements.

Note: you can carry certain packages containing Category C or Exempt materials on commercial flights, but the airline must be notified in advance. It is the pilot's decision whether the package will be allowed on the plane, and they have the right to refuse at time of check-in.

8. TRANSPORT BY POST

Category A & B Goods

Category A and B infectious substances are **PROHIBITED by Australia Post in international mail**.

Infectious substances may be posted domestically from the University under very strict conditions set out in Section D10.3 of the 'Dangerous & Prohibited Goods & Packaging Post Guide (2009)'. Additional charges will apply.

Please note that many Universities have trouble sending Category B material domestically with Australia Post, and despite the detailed instructions issued by them, there is no guarantee that they will accept your material. It is therefore advised that a recognised courier be engaged to transport any infectious material within Australia.

If sending any Category B biologicals from the University via Australia Post, the following is required:

- The Australian Recipient/Addressee must be a recognised laboratory
- The University is clearly identified as the sender
- The packaging and labelling comply with IATA Packing instructions* and must contain an itemised list of contents between the inner and outer packaging
- The shipper must ensure that the goods are prepared in such a manner that they arrive at their destination in good condition and that they present no hazard to people or animals during shipment.

Category C & Exempt

Exempt category material can be posted provided that the destination country permits this. Some countries will not accept any biological materials by post. It is your responsibility to determine what the destination country will permit. See the Australia Post International Post Guide for further information: http://auspost.com.au/parcels-mail/international-post-guide.html

Australia Post requires use of specified markings and a Shippers declaration for domestic or overseas postage of Exempt biological materials. Please contact Australia Post to obtain the relevant documents.

9. TRANSPORT BY ROAD OR RAIL

Category A & B Goods

The Australian Code for the Transport of Dangerous Goods by Road and Rail 7th Edition requires Category A and B biological material to be packed and labelled as per the IATA air transport requirements.

Category A biologicals can only be transported by a trained driver in a specially equipped and labelled vehicle.

If you intend to use your car to transport Category B biologicals for work purposes, you should first check with your car insurance company to see if your car insurance is valid for this purpose. The use of personal vehicles for this type of transport is discouraged. It is recommended that you use an experienced commercial courier instead.

Category C & Exempt

In general, it is preferable to use an experienced commercial courier to transport biological materials whenever possible. Where this is not possible, it is recommended that Flinders University staff use University vehicles rather than private cars for work-associated transport of Exempt or Category C biological materials.

In addition to the requirements for packaging biological materials, at Flinders University consult local WHS representatives for advice regarding requirements for vehicular transport of packages where liquid nitrogen or dry-ice is used as a coolant. A risk assessment will be required, and requirements will be set on a case-by-case basis.

Documentation and any coolants must be placed between the secondary and outer packaging so that documentation is accessible to the transporter without opening the inner package.

The package must be secured to the vehicle so that it will remain in position under adverse conditions (e.g., in an accident or during heavy braking conditions). It should be segregated from other material.

10. PACKAGING REQUIREMENTS

Category A & B Goods

Packaging and labelling for Class 6.2 Infectious Substances must meet CASA/IATA requirements. Category A and B infectious material in general must be triple packed in IATA approved packaging (the packaging will be stamped with an IATA approval). These packages have been drop tested and pressure tested and are available commercially.

Prior to arranging packaging by the University's CASA trained representative, you must purchase an IATA approved packaging system suitable for the materials you are transporting.

Examples of commercial suppliers of approved packaging include:

- Marair - https://marair.com.au/shop/
- Biobottle: https://www.biobottle.com.au/
- DG Air Freight: https://www.dgair.com.au/shop/product-category/life-science-packaging/

- Ambient packaging systems are designed to be transported at room temperature. Insulated systems are available for shipments requiring cooling – if using dry ice ensure that you purchase a dry ice compatible packaging system.
- Category A materials must meet IATA packing instruction 620
- Category B materials must meet IATA packing instruction 650
- Contact ibcadmin@flinders.edu.au for assistance with purchasing decisions if required.

You are not permitted to pack Category A and B biological material for transport by air unless you have done a CASA approved training course. This certification must be renewed every 2 years. At Flinders University, contact the Biosafety Officer (ibcadmin@flinders.edu.au) if you require assistance with packaging these goods – ensure plenty of prior notice is given, and that you have obtained required packaging materials and labels.

PACKAGING PRINCIPLES

The packaging must consist of three components:

1. Inner packaging, consisting of:
    - Watertight/sift proof primary receptacle(s) containing not more than 1 L and weighing not more than 4 kg.
    - Watertight/sift proof secondary packaging.
    - Absorbent material in sufficient quantity to absorb the entire contents, placed between the primary receptacle(s) and the secondary packaging.
    - Cushioning material to secure the secondary packaging within the outer (tertiary) packaging.
    - Where multiple primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated from each other to prevent contact between them.

2. An itemised list of contents must be enclosed between the primary receptacle and the secondary packaging.

3. A rigid outer (tertiary) packaging must be used. At least one surface of the outer packaging must have a minimum dimension of 100 mm.

All packaging must meet IATA drop-test and internal pressure requirements, and be UN marked for this purpose.

Category C & Exempt

For all transport of Exempt or Category C materials by air or surface transport methods, the packaging must consist of **three** components (also known as triple packaging or triple containment):

1. Primary receptacle
2. Secondary packaging
3. Outer packaging

All layers of packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport. Packaging shall be constructed and closed to prevent any loss of contents that might be caused under normal conditions of transport, or by vibration or changes in temperature or humidity.

If dry-ice, liquid nitrogen, or any other coolant that will release a gas is used in transport, then ventilation of the package is required.

Primary receptacle

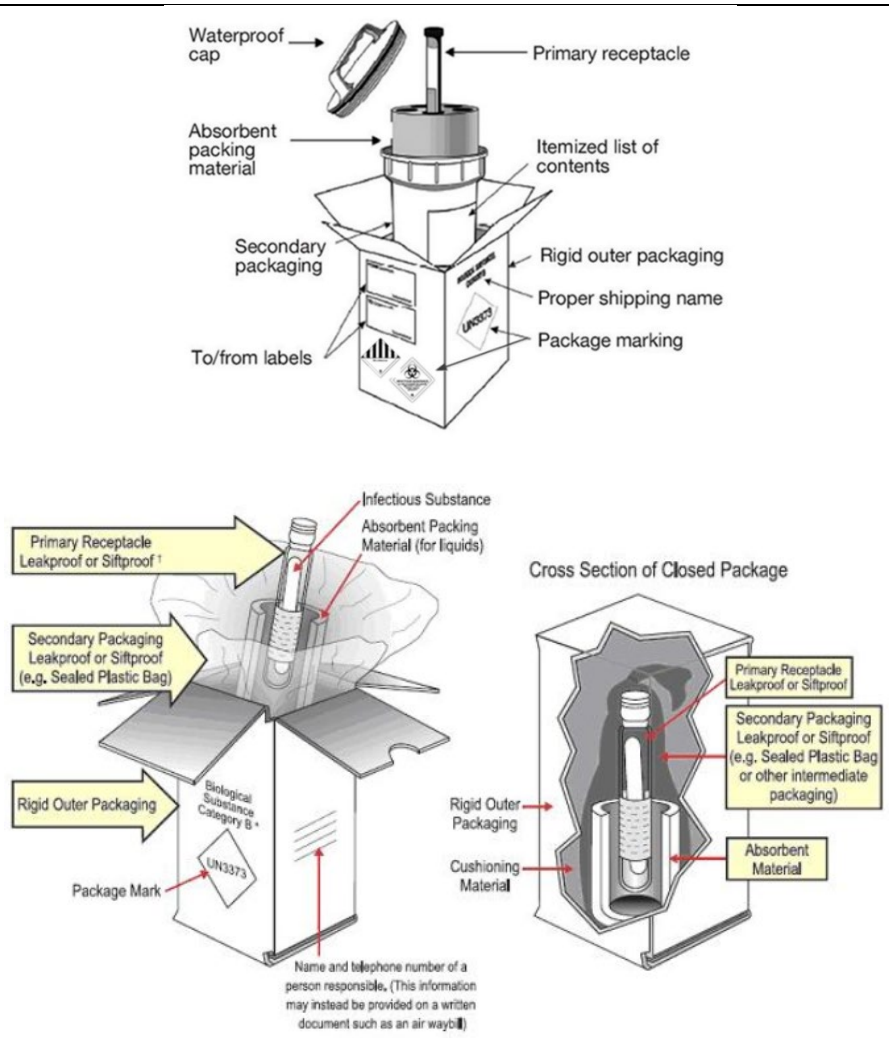
- The primary receptacle(s) shall be leakproof.
- Primary receptacles shall be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents.
- If multiple primary receptacles are placed in a single secondary packaging (e.g., many small tubes in one outer container), they shall be either secured together (e.g., using a rubber band), individually wrapped, or separated to prevent contact between them (e.g., held in a tube rack).
- Examples of primary receptacles include: a screw capped container or tube or a plastic tube (e.g., Eppendorf) sealed with tape.

Secondary packaging

- The secondary packaging shall be leakproof.
- Secondary packaging(s) shall be secured in outer packaging with suitable cushioning material. Any leakage of the contents shall not compromise the integrity of the cushioning material or of the outer packaging.
- For liquids, absorbent material should be present in case of leakage and for cushioning, if necessary. Acceptable absorbent materials include cellulose wadding, cotton balls, liquid-absorbent packets, paper towel or shredded newspaper.
- A liquid nitrogen dry shipper or a foam/polystyrene cooler (commonly referred to as an esky) **shall not** be used as secondary packaging.
- Examples of secondary packaging include: a snap-lock plastic bag, an empty, clean screw cap jar.

Outer packaging

- The outer packaging shall be a solid, strong, and durable container fitted with a secure closure to prevent loss of contents under normal transport conditions (strong adhesive tape is permitted).
- Foam/polystyrene coolers (commonly referred to as an esky) **shall not** be used as the outer packaging.
- Examples of outer packaging include: a sturdy box or solid plastic esky (not a foam/polystyrene esky).



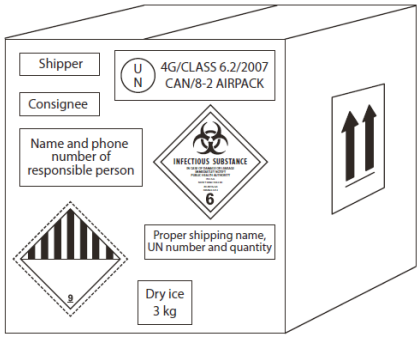
Examples of triple-packing systems for Category A, B, C, and exempt samples

11. LABELLING & DOCUMENTATION REQUIREMENTS

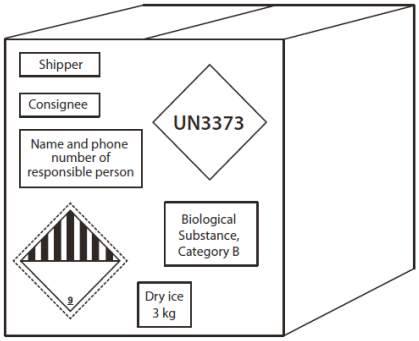
Category A & B Goods

Some packages may require specific dangerous goods markings – e.g., Class 6.2 infectious and Class 9 miscellaneous (for dry ice and/or GMOs) labels.

In addition, they must also include the appropriate UN numbering on the package, the appropriate shipping name and include an itemised list of contents and a Shipper's Declaration. The courier may provide a Shipper's Declaration form for the Dangerous Goods packer to complete, otherwise a template is provided by IATA: https://www.iata.org/en/programs/cargo/dgr/shippers-declaration/



Example Labelling for Category A



Example Labelling for Category B

Labelling on the outside of the outer packaging must include, at minimum, the following:

Category	CATEGORY A	CATEGORY B
Correct shipping name(s)	• Infectious Substances, affecting humans • Infections Substances, affecting animals only	Biological Substance, Category B
UN number	• Infectious Substances, affecting humans = UN 2814 • Infections Substances, affecting animals only = UN 2900	UN 3373
Required markings	• Shipper's name, address, and telephone number • Receiver's name, address, and telephone number • Name and telephone number (24 hr) of responsible person (transporter) • UN specification marking (will be part of IATA approved packaging) • Proper shipping name and UN number • Dry-ice labelling & Miscellaneous DG label (Class 9) (if required) • Package orientation label (if primary sample exceeds 50 mL)	• Shipper's name, address, and telephone number • Receiver's name, address, and telephone number • Name and telephone number (24 hr) of responsible person (transporter) • Proper shipping name and UN number • Dry-ice labelling & Miscellaneous DG label (Class 9) (if required) • Package orientation label (if primary sample exceeds 50 mL)
Labels	 Minimum size 50 mm x 50 mm  For all shipments via air	 BIOLOGICAL SUBSTANCE CATEGORY B Minimum size 50 mm x 50 mm

Category C & Exempt

The following labelling requirements apply for all transport of Category C and Exempt category materials by air or surface transport methods:

- A brief description of the material (e.g., Exempt Human Specimens, Exempt Animal Specimens, Category C Non-Infectious Biological Material) must be provided on the outer packaging.
- Name, physical address, and organisation of sender must be provided on the outer packaging (do not use PO Box numbers).
- Emergency contact telephone number must be provided on the outer packaging.
- Name and physical address of recipient must be provided on the outer packaging (do not use PO Box numbers).
- Orientation labels should be used on the outer packaging if the package contains 50 mL or more of liquid.
- If using Australia Post, you must obtain from them the specified markings and Shipper's declaration.

- If coolants are used, indicate their presence and (where applicable) UN number on the outer packaging.
- Documentation identifying the contents of the primary receptacle shall be outside the secondary package (between the secondary packaging and the outer packaging).

An example declaration form is provided below for guidance. This can be affixed to the outside of the outer packaging.

Receiver's Name and Address:	
Receiver's Contact Number:	
Sender's Name and Address:	
Sender's Emergency Contact Number:	
Number of packages:	
Date:	
Print Name of Signatory:	
Signature:	

INFORMATION FOR TRANSPORT OF BIOLOGICAL MATERIAL

Please be aware that this biological material, as packaged, poses no direct risk to you or your transport vehicle. It should, however, be handled with care and consideration. For example –

a) The package should be transported directly to the receiver.
b) It should not be transported in the passenger compartment of your vehicle, but should be placed in a luggage compartment, for example in the boot or behind the cargo barrier of the vehicle.
c) It should not be stowed with, or near, food or food containers.

If the package you are transporting breaks, leaks, or becomes damaged, please follow the steps below:

1) Do not attempt to handle or interfere with any part of the package.
2) Ensure no other person(s) come into contact with the contents of the package.
3) As soon as practicable, contact the receiver or sender on the above numbers.

12. ASSEMBLY

You are not permitted to pack Category A and B biological material for transport by air unless you have done a CASA approved training course. This certification must be renewed every 2 years. At Flinders University, contact the Biosafety Officer (email: ibcadmin@flinders.edu.au) if require assistance with packaging these goods – ensure that this is arranged with plenty of notice and that you have procured the required packaging containers and labels ready for assembly.

1	Place primary receptacle into secondary packaging. If multiple primary receptacles are placed in a single secondary packaging, a rubber band may be used to secure them all. Alternately each primary receptacle may be individually wrapped or separated with absorbent material, bubble wrap, etc.
2	For transported liquids, place absorbent material around the primary receptacle, within the secondary packaging.
3	Place the secondary packaging into the outer packaging, with cushioning if required.
4	Place any required coolants between the secondary package and outer package.
5	Complete associated shipping declarations and paperwork.
6	Place documentation between the secondary package and outer package.
7	Seal outer packaging and place required labels on the outside of the box.

13. PACKAGING WITH COOLANTS

- If dry-ice, liquid nitrogen, or any other coolant that will release a gas is used in transport, then ventilation of the package is required. A dry shipper should be used where possible when transporting material in liquid nitrogen.
- Coolants may only be placed between the secondary and outer packaging. When placing the secondary container into the outer package, support must be provided to hold the secondary package in place without depending on the coolant material.
- Primary and secondary packaging must be able to maintain containment integrity at the temperature of the coolant used, as well as at the temperature or pressures that could be experienced if the coolant were to be lost.
- When coolants such as dry-ice, liquid nitrogen or any other chemicals are used in conjunction with packaging, it is important that handlers are aware of the hazards involved. It is a requirement that the outer packaging shall be marked to indicate their presence.
- If you are using dry ice (a Class 9 Dangerous Good), the following marking is required on the outer packaging:
    - "DRY ICE" (UN 1845)
    - Indicate the net weight (kg) of the dry ice
    - A miscellaneous dangerous goods Class 9 label is required
    - Ensure dry ice is packaged between the secondary and outer package.
    - Ensure ventilation of package so gas can escape.
- Where water ice or frozen packs are used as coolants, these must be placed outside of the primary package, and the outer package must be waterproof and sealed to prevent the escape of melted ice. Wherever possible, ice packs are preferred.
- In addition to the requirements for packaging biological materials, at Flinders University consult local WHS representatives for advice regarding requirements for personal vehicular transport of packages where liquid nitrogen or dry-ice is used as a coolant. A risk assessment will be required, and requirements will be set on a case-by-case basis

14. REUSE OF PACKAGING CONTAINERS

Where contaminated secondary and/or outer packaging of biological materials is intended to be reused, it shall be decontaminated using an appropriate disinfectant (see Appendix F of AS/NZS 2243.3 for advice regarding suitable disinfectants).

Packaging shall be inspected before reuse. Where packaging exhibits signs of interior or exterior damage or deterioration, it shall not be reused. Any irrelevant markings and labels shall be removed from packaging before it is reused.

15. PROHIBITED TRANSPORT ACTIVITIES

1	It is prohibited to carry Class 6.2 Dangerous Goods within vehicles carrying passengers or crew, or to send them by airmail.
2	It is prohibited to carry Category A infectious materials in a private or University vehicle. Such items must be transported by a trained courier in a specially equipped and labelled vehicle.
3	It is prohibited to pack Category A and B biological material for transport by air unless you have current CASA certification.
4	It is prohibited to transport animals or invertebrates infected with Class 6.2 Category A or B infectious microorganisms.
5	Category A materials may not be shipped by specific couriers or to specific countries – contact the relevant courier for further information.

6	Shipment of Category B materials is prohibited to the following countries due to restrictions in the recipient countries: China, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Uzbekistan, Albania, Kosovo, Montenegro, Bahrain.
7	Microorganisms and biological products specified in Categories 1C351 – 1C354 of the Defence Strategic Goods List (DSGL) cannot be sent overseas without first obtaining a Defence Export Permit and clearance from the Department of Immigration and Border Protection.

16. APPLICABILITY

These procedures are applicable to all persons involved in the transport of biological goods, including those arranging shipping with a commercial courier.

17. CONTACTS

Biosafety Officer	Belinda Cox	ibcadmin@flinders.edu.au ph. (08) 82013436

18. DEFINITIONS

Biological products	Products derived from living organisms, for example vaccines.
Category A	An infectious substance which is transported in a form that, when exposure to it occurs, can cause permanent disability, or life threatening or fatal disease to humans, animals, or plants.
Category B	Infectious material that does not meet the criteria for inclusion in Category A and is known or suspected of containing less virulent pathogens (e.g., risk group 2 pathogens, as defined in AS/NZS 2243.3).
Category C	Applicable only within Australia for surface transport (i.e., road or rail). Includes biological material with a low probability of causing disease in humans, animals, or plants. This covers human, animal or plant samples including excreta, secreta, blood and its components, tissues and tissue fluids, and cell cultures not belonging to Category A or B biological material.
Cultures	Product of the intentional propagation of microorganisms.
Exempt specimens	Defined in the IATA *Dangerous Goods Regulations* and applicable internationally for samples transported by surface or air. Includes samples where there is minimal likelihood that pathogens are present – e.g., a urine sample being sent for diagnostic testing.
Infectious substances	Substances that are known or are reasonably expected to contain pathogens.
Patient specimens	Human or animal bodily products or materials, including but not limited to excretions, secretions, blood, tissue, and body parts.
Pathogens	Microorganisms including bacteria, viruses, rickettsiae, parasites and fungi, and other agents such as prions that can cause disease in humans, animals, or plants.
Shipping names	Designated labelling, dependent on category and UN code of the material being transported. See Labelling and Documentation Requirements for details on the proper shipping names for different materials.
UN codes	Designated labelling, dependent on category and type of material being transported. See Labelling and Documentation Requirements for details on the proper UN codes for different materials under Categories A and B.