BIOCOMPLIANCE GUIDANCE DOCUMENT





Guidelines for the Safe and Compliant Transport of Regulated Biological Materials

Glossary:

GMO: Genetically modified organism

OGTR: Office of the Gene Technology Regulator

DAFF: Department of Agriculture, Fisheries and Forestry

CASA: Civil Aviation Safety Authority

IATA: International Air Transport Association

PC2: Physical Containment Level 2

Overview:

This document provides comprehensive guidance for the safe and compliant transport of regulated biological materials, including genetically modified organisms (GMOs), biosecurity-controlled goods, and infectious substance. It is intended to provide an overview of the responsibilities, classification, packaging and transport procedures for regulated biologicals, and to provide information on where to find further technical information.

Information is provided to help researchers to remain compliant with relevant legislative requirements. Research groups are responsible for reviewing relevant legislation and standards, and for the preparation of Safe Operating Procedures (SOPs) and Risk Assessments incorporating requirements relevant to their work.

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INSTITUTIONAL BIOSAFETY COMMITTEE

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1. Personnel Responsibilities:

All personnel must understand and comply with relevant state, national and international regulations for shipping biological goods.

- IATA Certification personnel involved in packaging and labelling Category A and Category B
 goods for shipment must be trained by a CASA-approved training organisation. This requires
 completion of the combined course covering infectious substances, diagnostic specimens and dry
 ice. CASA-accredited training organisations are <u>listed on the CASA website</u>. Training must be
 renewed every 2 years.
- **Courier selection** personnel arranging the shipment of goods by a courier are responsible for ensuring that the company selected is trained and competent in the transportation of biological goods classified as dangerous goods, GMOs and/or biosecurity-controlled goods.
- **Documentation** the sender (shipper) must provide all required documentation (e.g., certifications, permits) required by the national authorities of the countries of export, transhipment and import.
 - For international shipments, use experienced logistics companies and check local requirements with the recipient.
- **Risk management** researchers must prepare risk assessments and SOPs for transport, including addressing incidents which may occur during transport, such as spills, loss of samples, or other reasonably foreseeable emergencies.

Notify the <u>IBC</u> for incidents involving GMOs or infectious samples, and the <u>import compliance</u> team for incidents involving biosecurity-controlled goods.

2. Applicable Legislation and Guidelines

The transport of biological materials is regulated under state, national and international legislation. The list below summarises the most common legislation applying to transport of biological materials for research in Australia.

Legislation	Regulatory Authority	Regulations, Guidelines and Resources	Scope
Gene Technology Act 2000	OGTR	OGTR Guidelines for the Transport, Storage and Disposal of GMOs	Outlines the requirements for import, transport and export of genetically modified organisms and associated samples and waste.
Biosecurity Act 2015	DAFF	Approved Arrangement Biosecurity Containment Conditions as applicable for the level of containment prescribed for your biosecurity-controlled goods.	Outlines the requirements for import and transport of biosecurity-controlled goods.
Dangerous Substances Act 1979 (SA)	SafeWork SA	Dangerous Substances (Dangerous Goods Transport) Regulations 2023 (SA)	Outlines the requirements for the transport of biological samples classified as Dangerous Goods within South Australia. Refer to Sections 3 & 4 of this document for further information on dangerous goods classifications.
Australian Code for the Transport of Dangerous Goods by Road and Rail	National Transport Commission	Australian Code for the Transport of Dangerous Goods by Road and Rail	Outlines the requirements for the transport of biological samples classified as Dangerous Goods by road or rail within Australia. Refer to Sections 3 & 4 of this document for further information on dangerous goods classifications.

International Air Transport Association (IATA) Dangerous Goods Regulations (DGR)	IATA	The IATA DGR is not available freely online. Instead, search for the relevant packaging instruction numbers as specified in relevant sections of this document.	Outlines the requirements for the transport of biological samples classified as Dangerous Goods by air within Australia or internationally. Refer to Sections 3 & 4 of this document for further information on dangerous goods classifications.
South Australian biosecurity legislation (various)	Primary Industries and Regions South Australia (PIRSA)	South Australian notifiable disease lists Interstate quarantine website	Restrictions apply to transporting certain biological materials (e.g., plants, livestock, soil, bee products, microorganisms associated with notifiable diseases) between states, to Kangaroo Island or the Riverland. Contact PIRSA for further information.
Convention on International Trade in Endangered Species (CITES)	Department of Climate Change, Energy, the Environment and Water (DCCEEW)	Check the CITES <u>list of affected</u> <u>species</u> and <u>additional domestic</u> <u>measures</u> and apply for permits via the <u>Wildlife Trade Office</u> .	An international agreement protecting threatened species of animals and plants. All import, export, and reexport of specimens from specific wild animals and plants requires a licence.
Environment Protection and Biodiversity Conservation Act 1999	DCCEEW	See the lists and information on the Wildlife Trade Offices' 'Do I need a permit' website.	Regulates the movement of all native animals, specific listed animals, plants and specimens from these to and from Australia. Permits are required for import, export and re-export.
Nagoya Protocol	DCCEEW	Department of Climate Change, Energy, the Environment and Water's website	Governs access and benefit-sharing relating to genetic resources from biological samples. The type of permit(s) you may need depends on where the samples are collected.

3. Classification of Biological Materials for Transport

The transport of biological materials is heavily regulated. Many biological samples have the potential to be hazardous to the health of people, animals or the environment and in many cases, biological materials are classified as dangerous goods.

The purpose of transport regulations is to ensure that goods remain packaged and contained throughout the transport activity, and that goods are labelled to ensure accurate identification for effective emergency response. To achieve this, the goods must be correctly classified.

The relevant transport legislation and packaging conditions will depend on:

- The types of goods being transported (e.g., microbiological samples, GMOs, biosecurity-controlled goods);
- Where the goods are being transported (e.g., on campus, domestically or internationally); and
- The method of transport (e.g., by road, rail, air, post, etc.).

The different scenarios are summarised in table 2, with information about applicable requirements and directing you to relevant sections of this document.

Table 2: Summary of applicable transport requirements for different transport scenarios for goods requiring up to PC2 level containment.

Transport activity type	Containment requirement	Accounting procedures required	Spill response procedures required	Security/restricted access required	Decontamination of containers before transport required	Relevant section of these guidelines
Between rooms within a building	Double containment	Recommended	Recommended	Yes	Yes	Section 9 andFor GMOs: 7For biosecurity: 8
Between floors within a building	Double containment	Recommended	Recommended	Yes	Yes	Section 9 andFor GMOs: 7For biosecurity: 8
Between buildings (transiting outside, not leaving campus)	Double containment	Yes	Yes	Yes	Yes	Section 9 andFor GMOs: 7For biosecurity: 8
Between campuses by public road	Varies depending on material transported	Yes	Yes	Yes	Yes	Sections 4, 10 and • For infectious/toxic microorganisms including GMOs: 5.4, 5.5 and 6.1 • For GMOs: 7 • For biosecurity: 8
Air	Triple containment	Yes	Yes	Yes	Yes	Sections 4, 5, 6 and For GMOs: 7 For biosecurity: 8
Post	Triple containment	Yes	Yes	Yes	Yes	Sections 4, 5, 6 and For GMOs: 7 For biosecurity: 8
Public road (by courier)	Triple containment	Yes	Yes	Yes	Yes	Sections 4, 5, 6 and For GMOs: 7 For biosecurity: 8
Sea	Triple containment	Yes	Yes	Yes	Yes	Sections 4, 5, 6 and For GMOs: 7 For biosecurity: 8

4. Transport via Air, Post, Public Road, Rail, Sea - Classification as Dangerous Goods

Infectious microorganisms, GMOs and associated samples are classified as dangerous goods for transport when they are transported by air, post, public road, rail or sea (i.e., when transported off campus). This includes when transporting by road between campuses. Some biosecurity-controlled goods will also be classified as dangerous goods if they contain microorganisms or GMOs.

Dangerous goods are classified according to United Nations criteria. Biological materials fall under the following high-level classifications:

- Class 6 Toxic and Infectious Substances
 - O Class 6.1 Toxins from plant, animal or bacterial sources
 - Class 6.2 Infectious substances including biological products, cultures, patient specimens (animal or human) and medical or clinical wastes
 - Category A Infectious Substances see Table 3
 - UN2814 Infectious substances, affecting humans
 - UN2900 Infectious substances, affecting animals
 - Category B Biological Substances see Table 3
 - UN3373 Biological substance, Category B
 - UN3291 Unspecified clinical waste (not otherwise specified)
 - Exempt human/animal specimens see Table 3
- Class 9 Miscellaneous dangerous goods
 - o Includes non-infectious GMOs
 - UN3245 Genetically Modified Organisms (GMOs) or Genetically Modified Microorganisms (GMMOs)
 - o Includes dry ice when used as a coolant for other categories
 - UN1845 Dry ice (Carbon Dioxide Solid)

Important notes:

- Transport of GMOs is also regulated under the Gene Technology Act 2000 and must be undertaken in accordance with OGTR Guidelines for the Transport, Storage and Disposal of GMOs in addition to the Dangerous Goods requirements.
- Transport of biosecurity-controlled goods is also regulated under the *Biosecurity Act* 2015 and must comply with conditions set out in the corresponding Approved
 Arrangement requirements, permits and movement directions in addition to any applicable Dangerous Goods requirements.
- Transport of live animals is not described under the IATA Dangerous Goods Regulations, but there are conditions within other legislation prohibiting the transport of live animals knowingly infected with infectious microorganisms.

A summary of the different dangerous goods categories for biological materials is provided in Section 5 and Table 3, and further information about the packaging and labelling for these is provided in Section 6.

5. Dangerous Goods Category Descriptions

5.1 UN numbers and proper shipping names

- A UN number is a four-digit number used to identify dangerous goods for transport that are recognised internationally. Correct packaging for different shipment types will often be sold pre-labelled with this number.
- A proper shipping name is a standardised, internationally recognised name used to identify
 hazardous or dangerous materials during transportation, to ensure proper classification,
 labelling and documentation according to regulations.

5.2 Packing instructions

Packing instructions are a set of standards published in the IATA Dangerous Goods Regulations (DGR), that detail the specific requirements for packaging, labelling and preparing dangerous goods for transport. These are summarised for biological goods throughout Section 6 and 7 of this document.

The packing instruction number is a reference to the relevant instruction in the IATA DGR and can often be used to access the packaging instructions online.

Important note: You are not allowed to pack Category A and/or Category B biological material for transport by air unless you have done a Civil Aviation Safety Authority (CASA) approved training course. This certification must be renewed every two years.

5.3 Class labels

These are the labels that are applied to the outer packaging to alert other users to the risks presented by the packaged goods. Class labels have a specific format, design and colour in accordance with the Dangerous Goods Regulations, and display the UN number assigned to the goods.

5.4 Category A Infectious Substances



Category A infectious substances are defined as those that are likely to contain infectious microorganisms (bacteria, viruses, fungi) capable of causing permanent disability or life-threatening fatal disease in otherwise healthy humans or animals when exposure occurs.

The IATA regulations provide a list of indicative microorganisms that are examples for Category A classification, and a copy of the list is provided in Appendix A. Infectious substances affecting humans are classified as UN2814 and those affecting animals are classified as UN2900.

Important note: transport by public road, rail, sea, air or post of live animals infected with Category A Infectious Substances is prohibited. Transport of Category A Infectious Substances by post is also prohibited.

5.5 Category B Biological Substances



Category B biological substances are microorganisms, or human or animal specimens (e.g., blood, tissue, fluids) which do not contain any of the pathogens from Category A.

Important note: transport by road, rail, sea, air or post of live animals infected with Category B Biological Substances is prohibited.

5.6 Category C Specimens / the "Exempt Category"

The Exempt Category (Exempt Biological) is a sample where there is minimal likelihood that pathogens are present (e.g., some diagnostic samples such as urine). These are not regulated as dangerous goods when shipped via air, however the specimens must still be packaged and marked in a certain way to identify them to shippers.

Within Australia, exempt category goods are referred to as Category C when they are transported by road or rail.

Important note: The 'exempt category' is a designation used for biological goods for transport and is not the same as exempt GMOs. Some exempt GMOs will be classified as Category B biological substances for the purpose of transport.

Examples of exempt/Category C goods include:

- Patient specimens for which there is minimal likelihood that pathogens are present.
- Biological samples containing risk group 1 microorganisms that are not likely to cause disease in humans or animals.
- Biological materials that have been fixed or preserved so that any microorganisms present are inactivated or non-viable.
- Environmental samples including food or water that are not considered to pose a risk of infection.
- Dried blood spots for diagnostic testing.

Table 3: Summary of the classification of different biological goods for transport, and relevant identification, instructions and other considerations.

Dangerous Goods Classification	Biological goods general description	Dangerous Goods Category	Proper Shipping Name	UN Number	Packing Instructions (from IATA)	Prohibitions	Other considerations
Class 6, Division 6.2	infectious microorganisms and infectious samples*	Category A	Infectious substance, affecting humans Infectious substance, affecting animals	UN 2814 UN 2900	P620	Must not be transported on passenger aircraft or public transport. Prohibited in domestic and international post.	GMOs that are also classified as Category A must be packaged as Category A goods when transported by public roads, by air, rail, or sea. Transport of Category A substances by post is prohibited.
		Category B	Biological substance, Category B	UN 3373	P650	Prohibited in domestic and international post. Cannot be transported on public transport.	GMOs that are also classified as Category B must be packaged as Category B goods when transported by public roads, by air, rail, or sea. Transport of Category B substances by post is at the discretion of the postal service.
	Equipment contaminated with Category A infectious substances	Category A	Medical devices or equipment contaminated with or containing infectious substances in Category A	UN 2814 or UN 2900 as appropriate	Must be marked 'Used Medical Device' or 'Used Medical Equipment'	Must not be transported on passenger aircraft or public transport. Prohibited in domestic and international post.	
	Used medical devices or equipment <u>not</u> contaminated with Category A infectious substances	Exemption when no Category A present	Medical devices, medical equipment	N/A	Triple packaging		
	Clinical/diagnostic specimens	Exempt human/animal specimens	Exempt human/animal specimens	N/A	Triple packaging system	Note that some international countries will not accept any biological material sent by mail. It is your responsibility to check the requirements of the recipient country.	
Class 9	Non-infectious genetically modified organisms	GMOs not classified as either Category A or Category B infectious substances	Genetically Modified Organisms (GMOs) or Genetically Modified Microorganisms (GMMOs)	UN 3245	P904 (ICAO/IATA PI 959)	Note that some international countries will not accept any biological material sent by mail. It is your responsibility to check the requirements of the recipient country. Cannot be transported on public transport.	Class 9 conditions for the shipping of GMOs applies to any transport of GMOs on public roads, by air, rail, sea or post. The OGTR Guidelines for the Transport, Storage and Disposal of GMOs also apply for any domestic transport of GMOs.
	Coolants – dry ice	Miscellaneous dangerous good	Dry ice (Carbon Dioxide Solid)	UN 1845	P954	If transporting via passenger aircraft, approval is required from the airline carrier, and maximum volume limits apply. Must not be taken on public transport.	These conditions apply only when used as a coolant for biological substances described above.

Dangerous Goods Classification	Biological goods general description	Dangerous Goods Category	Proper Shipping Name	UN Number	Packing Instructions (from IATA)	Prohibitions	Other considerations
Class 2, Division 2.2	Coolants – liquid nitrogen	Nonflammable gas, cryogenic liquid	Nitrogen, refrigerated liquid	UN 1977	P203 Comply with all requirements of Division 2.2, Packing group III	Must not be transported by private vehicle. Prohibited in domestic and international post. Strict prohibitions apply – contact couriers or aircraft carriers for advice before shipping. Must not be taken on public transport.	
N/A	Items not subject to dangerous goods regulations	Biological materials not subject to dangerous goods regulations	N/A	N/A	N/A	Note that some international countries will not accept any biological material sent by mail. It is your responsibility to check the requirements of the recipient country.	

^{*}See Appendix A for indicative list of Category A infectious substances. Category B includes any microorganism or sample containing a microorganism that is not defined as Category A.

6. Packaging and Labelling Requirements for Biological Dangerous Goods

Detailed requirements for the packaging and labelling of biological goods are provided in the IATA Dangerous Goods Regulations. Below is a summary of the requirements for each class.

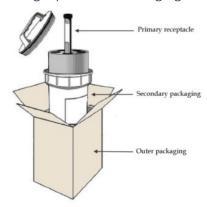
6.1 Packaging and Labelling Category A and B Dangerous Goods for Transport

It is important that any Category A or B (Class 6.2) infectious substances are packaged to meet CASA/IATA requirements. Refer to the IATA Dangerous Goods Regulations or contact a courier who provides Dangerous Goods Shipping for further information.

Important note: You are not allowed to pack Category A and/or Category B biological material for transport by air unless you have done a Civil Aviation Safety Authority (CASA) approved training course for the transport of infectious substances. This certification must be renewed every two years.

Courier companies who provide Dangerous Goods shipping options can often provide a packaging service where a CASA approved person is not available within your team or the technical services team for your faculty.

Category A and B Packaging:



A triple packaging system is the minimum required for packaging of Class 6.2 (Category A and Category B) material. Triple packaging consists of three layers: (1) a leakproof primary container; (2) a leakproof secondary container; (3) rigid outer packaging.

The type of packaging used for the secondary and outer packaging for Category A must be UN approved and stamped with an official approval. For Category B the package must have met certain package quality tests. These types of packages have been specially designed with robust and impervious construction, secure locking, and where applicable, with appropriate ventilation for coolants.

To find suitable packaging, you can search for packaging sold by courier companies that is rated as suitable for Category A (Un 2900 or UN 2814) or Category B (UN 3373) biological materials. Bio Bottles are a common, recognised secondary packaging option. General requirements are outlined below.

Category A and B Primary Container:

This is the container immediately surrounding the sample (e.g., a screw-capped Eppendorf or Falconer tube).

- Must be leakproof, or for solid materials, sift proof.
- Must be capable of containing the infectious substance under all conditions of transport, including temperature changes that may cause defrosting.
- Should be non-breakable the use of glass is discouraged.

- Must not contain any sharps (e.g. vacutainer with needle).
- Must not be a flip-top tube or similar. Screw-capped lids are required at minimum, and the screw-capped lid must be secured (e.g., parafilm or tape).
- Must be packed into the secondary container with enough absorbent material (e.g., paper towels, cellulose wadding, cotton balls) surrounding it to absorb the full volume of all fluids in case of breakage.

Category A and B Secondary Container:

This is the container enclosing the primary container and is used to protect the primary container and to capture any leakage in the event of damage to the primary container (e.g., a Bio Bottle, sealed specimen bag).

- Must be leakproof, or for solid materials, sift proof.
- It is possible to place multiple primary containers into one secondary container if there is adequate padding/cushioning material between the primary containers to prevent them becoming damaged during transport. Each primary container must be individually wrapped if more than one are placed into the secondary container.
- The secondary container must be capable of withstanding, without leakage, specific conditions during transport e.g., must withstand minimum pressure of 95 kPA and temperatures between -40°C to +55°C.
- An itemised list of the contents of the package must be included between the secondary container and the outer packaging.

Category A and B Outer Packaging:

A rigid outer shipping container (e.g., a sturdy, insulated fibre board box) that the secondary container(s) are placed into. The outer packaging protects the contents from damage while in transit.

Important note: Category A outer packaging must be UN approved and stamped.

- Must be rigid.
- Must have a least one surface with a minimum dimension of 100 mm x 100 mm.
- Must be labelled with appropriate class and category labels (see below).
- Where coolants such as dry ice are required, refer to section 6.4.

Category A and B Labelling:

The outer packaging must display all details listed in Table 4 below. Do NOT put the species name on the shipping labels or anywhere on the outside of the package.

Examples of packaging and labelling are provided in Figure 1 and 2 below.

Category A and B Documentation:

For both Category A and B goods, an itemised list of the contents must be provided and placed between the secondary container and the outer packaging (i.e., inside the box).

For category A goods, a shipper's declaration must be completed, in addition to a consignment note or airway bill. See an example shipper's declaration in Appendix B.

For Category B goods, a shipper's declaration is not required. However, a consignment note or airway bill is required.

Table 4: Labelling for outer packaging on Category A and B shipments

Label type	Category A Labels	Category B Labels
UN number	UN2814 for substances affecting humans UN2900 for substances affecting animals	UN3373
Proper shipping name	"Infectious substances, affecting humans" "Infectious substances, affecting animals"	Biological substance, Category B
Hazard class label	INFECTIOUS SUBSTANCE IN CASE OF DAMAGE OR LEAKAGE IMMEDIATELY NOTIFY PUBLIC HEALTH AUTHORITY Minimum size 50 mm x 50 mm	UN3373 Minimum size 50 mm x 50 mm
Other required labels	 Shipper's (sender's) contact information including name, address Recipient's contact information including name, address and phone number Name and 24-hour phone number of emergency contact Total volume and weight of infectious substance Package orientation label on two opposite sides of the package (if package contains ≥ 50mL) UN specification marking (to confirm that outer package is UN approved) Labels for dry ice, where applicable (see section 6.4) Cargo aircraft only label 	 Shipper's (sender's) contact information including name and phone number Recipient's contact information including name, address and phone number Labels for dry ice, where applicable (see section 6.4) Name and 24-hour phone number of emergency contact either on outer packaging or on airway bill/consignment note Package orientation label on two opposite sides of the package (if package contains ≥ 50mL)

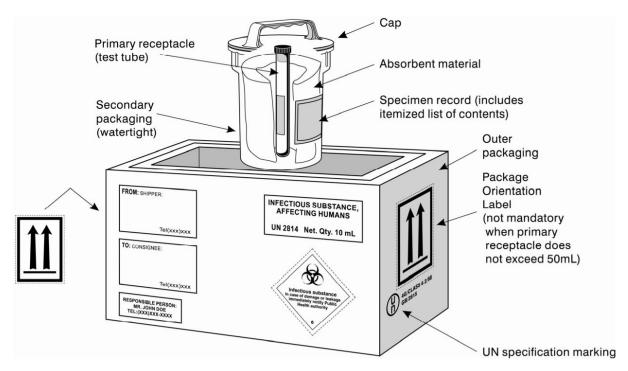


Figure 1: Example Category A (UN 2814 or UN 2900) packaging (from: WHO Guidance on regulations for the transport of infectious substances)

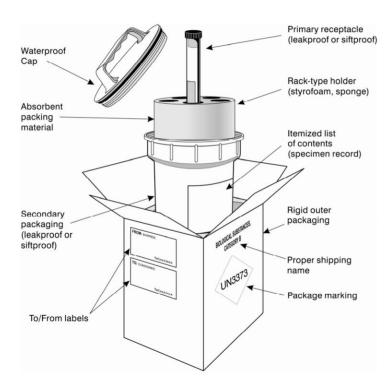


Figure 2: Example Category B (UN 3373) packaging (from: WHO Guidance on regulations for the transport of infectious substances)

6.2 Packaging and Labelling Category C/ 'Exempt Category' Biologicals for Transport

A triple packaging system is required for packaging of Class Exempt and Category C material. Triple packaging consists of three layers: (1) a leakproof primary container; (2) a leakproof secondary container; (3) rigid outer packaging.

Unlike Category A and B packaging, this packaging does not need to be tested or certified.

Exempt/Category C Primary Container:

This is the container immediately surrounding the sample (e.g., blood tube, urine container, screw-capped tube).

- Must be leakproof, or for solid materials, sift proof.
- Should be non-breakable the use of glass is discouraged.
- Must not be a flip-top tube or similar. Screw-capped lids are required at minimum, and the screw-capped lid must be secured (e.g., parafilm or tape).
- Must be packed into the secondary container with enough absorbent material (e.g., paper towels, cellulose wadding, cotton balls) surrounding it to absorb the full volume of all fluids in case of breakage.

Exempt/Category C Secondary Container:

This is the container enclosing the primary container and is used to protect the primary container and to capture any leakage in the event of damage to the primary container (e.g., a large screw-capped tube, or a sealed specimen bag).

- Must be leakproof, or for solid materials, sift proof.
- It is possible to place multiple primary containers into one secondary container if there is adequate padding/cushioning material between the primary containers to prevent them becoming damaged during transport.
- An itemised list of the contents should be placed between the secondary container and the outer packaging.

Exempt/Category C Outer Packaging:

An outer container that has adequate strength for its capacity, mass and intended use (e.g., a sturdy box, despatch satchel) that the secondary container(s) are placed into. The outer packaging protects the contents from damage while in transit.

- Must have a least one surface with a minimum dimension of 100 mm x 100 mm.
- Must be labelled with appropriate class and category labels (see below).
- Where coolants such as dry ice are required, refer to section 6.4.

Exempt/Category C Labelling:

The outer package must be labelled with:

- Name and address of the sender do not use PO Box addresses
- Name and address of the recipient do not use PO Box addresses
- The words "Exempt human specimens" or "Exempt animal specimens" as appropriate.

- Orientation labels on two opposite sides of the package, if the package contains 50 mL or more of liquid.
- Labels for dry ice where applicable see section 6.4.

An example of packaging and labelling is provided in Figure 3 below.

Exempt/Category C Documentation:

A shipper's declaration is not required for shipments by air, however, a consignment note or airway bill is required.

For transport via public road in Australia (Category C), a declaration form is required. An example is provided in Figure 4 below.

You must also complete any paperwork required by the courier or Australia post and, for international shipments, anything required by the destination country.

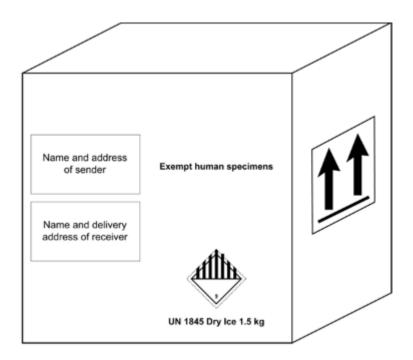


Figure 3: Example of packaging and labelling for Exempt human specimens (from National Pathology Accreditation Advisory Council).

Receiver's Name and Address: Receiver's Contact Number: Sender's Name and Address: Sender's Emergency Contact Number: Number of Packages: Consignment/Reference Note Number: 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.

In the event that 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.
- As soon as practicable, contact the receiver or sender on the above numbers.

Figure 4: Example declaration form for the transport of Category C biological goods by road (from AS 4834 [withdrawn]).

6.3 Contaminated Items

Materials or equipment that may be contaminated with Category A or Category B infectious substances must also be transported in accordance with the Dangerous Goods Regulations, as described in section 6.1.

6.4 Packaging and Shipping with Coolants (e.g., Dry Ice)

Biological samples can be shipped with appropriate coolants to keep them at a required temperature during shipment. The following requirements apply.

Ice and frozen gel packs

- Ice packs can be placed between the secondary container and the outer packaging.
- Wet ice can be placed in a leakproof container inside the outer package. Where wet ice is used, the outer packaging must also be leakproof.
- For wet ice, internal supports (e.g., foam packaging) must be provided to keep the secondary container in its original position as the dry ice dissipates.
- The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used.

Dry ice

Important note: You are not allowed to pack dry ice for transport by air unless you have done a Civil Aviation Safety Authority (CASA) approved training course covering dry ice transport. This certification must be renewed every two years.

- Any samples packaged with dry ice must be in packaging that is designed and constructed to
 permit the release of carbon dioxide gas and to prevent build-up of pressure that could
 rupture the packaging. A specially designed, insulated packaging, typically a polystyrene or
 wax-treated cardboard box is selected.
- The dry ice must be placed outside of the secondary container, between the container and the
 outer packaging. Internal supports (e.g., foam packaging) must be provided to keep the
 secondary container in its original position as the dry ice dissipates.
- The outer packaging must have ventilation to permit release of carbon dioxide gas that could rupture the packaging.
- The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used.

The outer packaging must be marked and labelled with:

- The proper shipping name: "Carbon dioxide, solid as coolant" or "Dry ice as coolant"
- UN number: UN1845
- A label specifying the weight of the dry ice in kilograms
- Hazard class label: Miscellaneous (Class 9) of minimum dimensions 50 mm x 50 mm.
- Other labels associated with the samples transported on dry ice.



Figure 5: Miscellaneous (Class 9) dangerous goods label

- Dry ice must be described on a shipper's declaration only when the dry ice is used as a refrigerant for dangerous goods that require a shipper's declaration (e.g. dry ice as a refrigerant for Category A goods).
- When a shipper's declaration is not required (e.g. for Biological Substances, Category B), the following information about dry ice must be contained in the 'Nature and Quantity of Goods' box on the air waybill or consignment note:
 - o The proper shipping name: "Carbon dioxide, solid as coolant" or "Dry ice as coolant"
 - o UN number: UN1845
 - o The weight of the dry ice in kilograms
 - o Hazard class: Miscellaneous (Class 9).

Substances consigned in liquid nitrogen:

- The transport of samples in liquid nitrogen must be undertaken following relevant regulations for dangerous goods (Division 2.2, UN 1977).
- A courier with authorisation to transport dangerous goods must be used for transport by public road, air, rail, sea, etc.
- A plastic primary receptacle must be used and must be capable of withstanding very low temperatures (e.g., a cryotube).
- The secondary packaging must be capable of withstanding very low temperatures.

7. Transport of Genetically Modified Organisms

7.1 International Transport (any mode) or Domestic Transport by Air

When shipping or transporting GMOs domestically by air, or internationally, GMOs are classified as Dangerous Goods. GMOs that do not meet the definition of an infectious substance are classified as Class 9, UN 3245 (Miscellaneous dangerous substances and articles, including environmentally hazardous substances).

Packaging:

A triple packaging system is required for packaging of Class 9 GMO material. Triple packaging consists of three layers: (1) a leakproof primary container; (2) a leakproof secondary container; (3) rigid outer packaging.

Unlike Category A and B packaging, this packaging does not need to be tested or certified.

Class 9 GMO Primary Container:

This is the container immediately surrounding the sample (e.g., screw-capped tube, zip-lock bag for seeds).

- Must be leakproof, or for solid materials, sift proof.
- Should be non-breakable the use of glass is discouraged.
- Must not be a flip-top tube or similar. Screw-capped lids are required at minimum, and the screw-capped lid must be secured (e.g., parafilm or tape).
- Must be packed into the secondary container with enough absorbent material (e.g., paper towels, cellulose wadding, cotton balls) surrounding it to absorb the full volume of all fluids in case of breakage.

Class 9 GMO Secondary Container:

This is the container enclosing the primary container and is used to protect the primary container and to capture any leakage in the event of damage to the primary container (e.g., a large screw-capped tube, or a sealed specimen bag).

- Must be leakproof, or for solid materials, sift proof.
- It is possible to place multiple primary containers into one secondary container if there is adequate padding/cushioning material between the primary containers to prevent them becoming damaged during transport.
- An itemised list of the contents should be placed between the secondary container and the outer packaging.

Class 9 GMO Outer Packaging:

An outer container that has adequate strength for its capacity, mass and intended use (e.g., a sturdy box, despatch satchel) that the secondary container(s) are placed into. The outer packaging protects the contents from damage while in transit.

- Must have a least one surface with a minimum dimension of 50 mm x 50 mm.
- Must be labelled with appropriate class and category labels (see below).
- Where coolants such as dry ice are required, refer to section 6.4.

Class 9 GMO Labelling:

The outer packaging must be marked and labelled with:

- The proper shipping name: "Genetically Modified Organisms (GMOs)" or "Genetically Modified Microorganisms (GMMOs)"
- UN number: UN3245
- Hazard class label: Miscellaneous (Class 9) and UN3245 labels of minimum dimensions 50 mm
 x 50 mm.
- For domestic transport by air, you must also add the acronym 'GMO' as a label on the outside of the outer container to comply with the requirements of the OGTR.

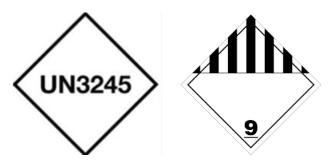


Figure 6: Non-infectious, non-toxic GMO and GMMO dangerous goods labels (both are required)

Documentation:

A shipper's declaration is not required for shipments by air, however, a consignment note or airway bill is required. You must complete any paperwork required by the courier and, for international shipments, anything required by the destination country.

7.2 Domestic Transport of GMOs – any transport method other than by air

The transport of genetically modified organisms domestically must comply with the requirements of the <u>OGTR Guidelines for Transport, Storage and Disposal of GMOs</u>.

The act of transporting a GMO is a 'dealing' under the Gene Technology Act 2000, and must be specifically approved by the University of Adelaide Institutional Biosafety Committee in your GMO approval, or by the OGTR where the GMO is handled under a licence. Records of Assessment or Licence Conditions may provide specific conditions regarding the transport of GMOs.

Check with your local Facility Manager or the Laboratory Animal Services team for local Standard Operating Procedures for the transport of GMOs.

General requirements for packaging of GMOs for transport

All GMOs transported domestically (other than by air) must be wholly contained within a sealed, unbreakable primary container. PC2 GMOs will then be further contained within a sealed, unbreakable secondary container. You should follow triple-packaging conditions where the GMO is infectious or toxic.

The type of container used will depend on the type of GMOs being contained. For example, a small liquid sample may be contained within a screw-capped Eppendorf tube as the primary container, GMO seeds may be placed in a sealed seed envelope which is taped closed, and for GMO mice the primary container may be an IVC cage that is clip-locked or otherwise taped or banded to enable it to remain closed during all reasonably expected conditions of transport.

Examples of secondary containers may be a larger, secondary screw-capped tube or a sample box that is taped or banded closed, or, for animals, an enclosed, lockable trolley with air vents that animal cages are placed inside of during transport.

The important considerations for choosing packaging are to ensure that the primary and secondary containers are sealed and unbreakable during reasonably expected conditions of transport, including if the containers are dropped.

When transporting GM and non-GM materials together, they should be physically separated to prevent cross-contamination, mix-up of samples, or for animals, interbreeding during transport.

General requirements for labelling of GMOs for transport

- The primary container must be labelled with details allowing the handler to identify the samples as GMOs or non-GMOs.
- The outside of the outermost container must be labelled with the acronym 'GMO' to allow any person encountering the packaging to identify that the item is, or contains, a GMO.
- The outside of the outermost container must be labelled with the name and mobile phone number of the person responsible for the GMOs.
- Where the GMOs are microorganisms, the outside of the outermost container must additionally have a biohazard label in place.
- When GMOs are being transported by a courier, the outside of the outermost container must also have the name, address and contact details of the sender and the recipient so that they can be contacted should the container be lost, damaged or misdirected.

Other general conditions of transport for GMOs

Authorised Persons

GMOs must be always accompanied by an authorised person during transport.

Only people, or classes of persons who are listed on the Record of Assessment or licence for the GMOs are authorised to handle GMOs during transport. Therefore, you must ensure that every researcher who handles GMOs under your approval has been listed on the application, and, where you engage couriers for transport, that the courier option has been selected and approved in your application.

Accounting procedures

When transporting GMOs out of the lab, you are required to implement an accounting system so that the loss of a GMO or failure of delivery can be detected. This requirement applies anytime that GMOs are transported outside of a single building.

Ensure that you count and record the number of samples/GMOs before transport occurs, and when you arrive at your destination (including before placing goods into storage). The OGTR may request copies of transport and accounting records as part of auditing procedures.

If sending GMOs to others, ensure that you count and record the number of samples sent and have the recipient confirm the number they have received back to you.

Remember that you are legally responsible for GMOs under your approval until they are received by a recipient who has their own approval, or until the GMOs leave

Australian territory in the custody of a courier who is experienced in GMO transport.

<u>Unintentional release and spill clean-up procedures</u>

When developing local procedures for the transport of GMOs, these should incorporate procedures to be implemented in the event of the escape, unintentional release, spill, leak or loss of a GMO during transport. When such an event occurs, you must make efforts as soon as safe and possible to located and return GMOs to containment, or to euthanise or render them non-viable. The incident must be reported to the IBC as soon as practicable, and the IBC will, where required, make a notification to the OGTR.

IBC contact details:

Email: ibc@adelaide.edu.au

Phone:

- Amanda Highet (Senior Research Compliance Officer) (08) 83136105; or
- Jess Hall (Research Compliance Officer) 08 83133059.

The IBC provides standard spill procedures on their <u>website</u> which should be implemented in the event of a GMO spill during transport. It is a good idea to have a copy of the spill poster with you when transporting GMOs outside of a building, and to have spill clean-up materials (disposable gloves, disinfectant and absorbent material) available during the transport activity.

Security

Access to the GMOs must be restricted, by any means that is effective, to only a person or class of persons mentioned in an IBC's record of assessment as having the appropriate training and experience to deal with the GMOs. Therefore, you must ensure that every researcher who handles GMOs under your approval has been listed on the application, and, where you engage couriers for transport, that the courier option has been selected and approved in your application. You must also ensure that the GMOs remain accompanied throughout transport or are otherwise secured. For example, you must

ensure that GMOs are in a secure location when left for collection in a loading area, or when left unattended prior to decontamination.

Decontamination of the outer container

The outside of the primary, secondary and any tertiary container must be wiped with disinfectant prior to exiting the facility. The disinfectant used must be suitable to achieve decontamination of the GMOs you are transporting. Ensure that you select transport containers with a non-permeable surface so that disinfection is possible.

8. Transport of Biosecurity-Controlled Materials

In addition to complying with dangerous goods classifications for imported biological goods, you must also comply with conditions set out by the Department of Agriculture, Fisheries and Forestry (DAFF) in the <u>Biosecurity Containment Approved Arrangement guidelines</u>, and associated permits and movement directions.

General (non-controlled) goods imported under a DAFF import permit must be transported in accordance with any conditions specified in the permit.

9. Transport Within Buildings or Within a Single Campus

Transport of biological samples within a building or within a single campus must comply with conditions outlined by the appropriate regulatory body:

- **Genetically Modified Organisms** refer to the <u>OGTR Guidelines for Transport, Storage</u> and Disposal of GMOs and section 7 of this document.
- Biosecurity controlled goods refer to the associated <u>Biosecurity Containment</u>
 <u>Approved Arrangement guidelines</u>, and associated permits and movement directions.

 Transport is only permitted between co-located approved arrangements, or as otherwise described in a movement direction.
- Samples containing microorganisms other than GMOs and biosecurity-controlled goods:
 - Risk group 1 samples must be packaged in a fully sealed primary container.
 - Risk group 2 samples must additionally be placed into a fully sealed secondary container.
 - The outside of the outermost container must be labelled with a biohazard symbol and the name and mobile phone number of the responsible researcher.
 - The outside of the container(s) must be disinfected before leaving the containment facility.
 - Viable risk group 3 and 4 samples are not currently permitted on campus as the university does not have any containment facilities suitable for handling these.

10. Transport Between Campuses

Transport of low-risk biological material between campuses by researchers is permitted providing that the goods do not meet the definition of Category A or Category B infectious material (see Section 5.5, 5.6 and 6.1). The materials must be accompanied by a person who is familiar with the contents and with procedures for the clean up of spills and/or notifications to the IBC.

Transport of biological samples (other than Category A and B infectious material) between campuses must comply with conditions outlined by the appropriate regulatory body where applicable:

- Genetically Modified Organisms refer to the OGTR Guidelines for Transport, Storage and Disposal of GMOs and section 7 of this document.
- Biosecurity controlled goods refer to the associated <u>Biosecurity Containment</u>
 <u>Approved Arrangement guidelines</u>, and associated permits and movement directions.

 Transport is only permitted between BC1 facilities, or as otherwise described in a movement direction.
- **Animal or human specimens:** should be transported per conditions for category C (exempt) goods described in Section 6.2.
- Samples containing risk group 1 microorganisms:
 - Must be packaged in a fully sealed primary container.
 - The outside of the outermost container must be labelled with a biohazard symbol and the name and mobile phone number of the responsible researcher.
 - The outside of the container(s) must be disinfected before leaving the containment facility.

Important note: Transport of Category A or B infectious materials is a heavily restricted activity in Australia and can only be undertaken by a courier who is authorised to transport dangerous goods. Therefore, a dangerous goods transport provider must be engaged to transport these materials between University of Adelaide campuses.

Appendices

Appendix A – Indicative Examples of Infectious Substances Classified as Category A

The list is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table, but which meet the same criteria must be assigned to Category A. If there is any doubt as to whether or not a pathogen falls within this category it must be transported as a Category A Infectious Substance.

UN number and	Microorganisms
proper shipping	
name	
	Bacillus anthracis (cultures only)
	Brucella abortus (cultures only)
	Brucella melitensis (cultures only)
	Brucella suis (cultures only)
	Burkholderia mallei – Pseudomonas mallei – Glanders (cultures only)
	Burkholderia pseudomallei – Pseudomonas pseudomallei (cultures only)
	Chlamydia psittaci – avian strains (cultures only)
	Clostridium botulinum (cultures only)
	Coccidioides immitis (cultures only)
	Coxiella burnetii (cultures only)
UN2814	Crimean-Congo haemorrhagic fever virus
_	Dengue virus (cultures only)
Infectious	Eastern equine encephalitis virus (cultures only)
substance,	Escherichia coli, verotoxigenic (cultures only) ¹
affecting humans	Ebola virus
	Flexal virus
	Francisella tularensis (cultures only)
	Guanarito virus
	Hantaan virus
	Hantaviruses causing haemorrhagic fever with renal syndrome
	Hendra virus
	Hepatitis B virus (cultures only)
	Herpes B virus (cultures only)
	Human immunodeficiency virus (cultures only)
	Highly pathogenic avian influenza virus (cultures only)
	Japanese Encephalitis virus (cultures only)
	Junin virus
	Kyasanur Forest disease virus
	Lassa virus
	Machupo virus
	Markovnov virus
	Monkeypox virus Mysobactorium tuborculosis (sulturos anh.) 1
	Mycobacterium tuberculosis (cultures only) ¹
	Nipah virus Omsk haemorrhagic fever virus
	Poliovirus (cultures only) Rabies virus (cultures only)
	Rickettsia prowazekii (cultures only)

	Rickettsia rickettsii (cultures only)
	Rift Valley fever virus (cultures only)
	Russian spring-summer encephalitis virus (cultures only)
	Sabia virus
	Shigella dysenteriae type 1 (cultures only) 1
	Tick-borne encephalitis virus (cultures only)
	Variola virus
	Venezuelan equine encephalitis virus (cultures only)
	West Nile virus (cultures only)
	Yellow fever virus (cultures only)
	Yersinia pestis (cultures only)
	, , , , , , , , , , , , , , , , , , ,
	¹ For surface transport, when the cultures are intended for diagnostic or
	clinical purposes, they may be classified as infectious substances of Category
	В.
	African swine fever virus (cultures only)
	Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus (cultures
UN2900	only)
	Classical swine fever virus (cultures only)
Infectious	Foot and mouth disease virus (cultures only)
substance,	Lumpy skin disease virus (cultures only)
affecting animals	Mycoplasma mycoides – Contagious bovine pleuropneumonia (cultures only)
	Peste des petits ruminants virus (cultures only)
	Rinderpest virus (cultures only)
	Sheep-pox virus (cultures only)
	Goatpox virus (cultures only)
	Swine vesicular disease virus (cultures only)
	Vesicular stomatitis virus (cultures only)

Appendix B – Example Shipper's Declaration

(source Belgian Biosafety Server)

