Transport of Biological Materials

1. Introduction

This guidance is provided to help you transport your biological materials and infectious substances in compliance with national and international law to protect health, safety and the environment. There are national and international regulations on the control of transport by road, rail, sea and air and for the import and export of dangerous goods. The detailed regulations and guidance are supplied by the national and international regulators. Please note that this guidance is only a brief summary of the requirements involved in the transport of biological materials and infectious substances and it does not cover all aspects of this complex field. You need to comply with the relevant regulations, use trained and competent staff and where needed take appropriate advice in order to ensure that transporting biological materials is carried out safely and securely.

2. Law

The transport of dangerous goods is governed by international and national regulations because of the international modes of transport and movement of goods. The United Nations (UN) produces the main rules for transport of dangerous goods called the Model Regulations on the Transport of Dangerous Goods which are then adopted as the basis for international, national and modal regulations. There are specific regulations and regulators for the different modes of transport by road, rail, air and sea.

The transport by road and rail is controlled under the International Carriage of Dangerous Goods by Road Regulations (ADR) and the International Carriage of Dangerous Goods by Rail Regulations (RID). The Health and Safety at Work Act and the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (CDG) is the main law which controls the transport of dangerous goods in the UK. The CDG Regulations implement European laws on the international carriage of dangerous goods by road and rail under ADR and RID. The regulations make extensive cross reference to the provisions in ADR and RID for specific details on classification, packaging, labelling and other requirements. The transport of dangerous goods by road is regulated by the Health and Safety Executive (HSE), Department for Transport (DFT), Environment Agency (EA), Scottish Environment Protection Agency (SEPA), Driver and Vehicle Standards Agency (DVSA) and Police. The transport of dangerous goods by rail is regulated by the Department for Transport (DFT) and Office of Rail and Road (ORR). The security requirements for transport of dangerous goods is regulated by the Department for Transport (DFT).

The transport of dangerous goods by air is controlled under the Technical Instructions for the Safe Transport of Dangerous Goods by Air Regulations produced by the International Civil Aviation Organization (ICAO) and the Dangerous Goods

Regulations (DGR) produced by the International Air Transport Association (IATA). The ICAO regulations are recognised as the legal requirements for the transport of dangerous goods by air and apply on all international flights. There are state and operator variations which are supplied in the ICAO Technical Instructions and IATA Dangerous Goods Regulations. The IATA DGR incorporates the ICAO regulations and is the guidance which is used in practice on the transport of dangerous goods by air. The transport of dangerous goods by air is regulated by the Civil Aviation Authority (CAA) and by the International Civil Aviation Organisation (ICAO). The CAA applies national legislation based on the ICAO Regulations for national flights in the UK. The transport of dangerous goods by sea is controlled under the International Maritime Dangerous Goods Code (IMDG) produced by the International Maritime Organisation (IMO). The transport of dangerous goods by sea is regulated by the Maritime and Coastguard Agency (MCA).

Many laws regulate the import and export of biological materials and infectious substances. The Control of Substances Hazardous to Health Regulations (COSHH) and Genetically Modified Organisms (Contained Use) Regulations (GMOCU) have specific notification requirements for the import and export of hazardous biological agents and genetically modified organisms. The Animal Health Act (AHA) and Specified Animal Pathogens Order (SAPO) requires a SAPO licence before any relevant animal pathogens are transported in the UK and the Importation of Animal Pathogens Order (IAPO) requires a licence for the import of any specified animal pathogens. The Plant Health Act (PHA) and Plant Health Orders (PHO) requires various licences or certificates for the possession or use and importation of plant materials, plant pathogens or pests.

3. Transport of Biological Materials

The transport, import and export of dangerous goods has to be conducted in compliance with national and international regulations. Biological materials which are dangerous goods must be safely transported from the sender to the receiver to prevent exposure or release to protect workers, the public and the environment. Biological materials which are not dangerous goods still have to be properly transported so they do not leak in transit and trigger safety or security alerts or cause unnecessary concern. The controls required for transport of dangerous goods is similar for the different modes of transport although materials sent by air generally have the most stringent standards. Remember that it is common for carriers to ship dangerous goods using multiple modes of transport like road and air in a journey. The transport of dangerous goods may involve additional restrictions imposed by operators and these are listed as operator variations in the various transport regulations. There are in addition many biological materials which require regulatory licences for their import or export.

The main responsibilities of shippers are classifying the biological materials or infectious substances, identifying the proper shipping name and UN number, correctly packaging, marking and labelling the packages, documenting the shipments

for transport and customs requirements, arranging transport with carrier and notifying the receiver of shipments. The risks of improper packaging and shipping include incidents, potential exposure to infectious substances, failed or delayed package delivery, shipments stopped at customs and prosecution. The benefits of proper transport include no incidents, protection of people and the environment, timely package delivery and compliance with national and international regulations. Please contact your School Biological Safety Adviser and School Biological Materials Transport Adviser if you need advice on the transport biological materials and infectious substances. You can also obtain specialist advice where needed on any complex issues involved in the transport biological materials and other dangerous goods from a Dangerous Goods Safety Adviser (DGSA) who are employed by dangerous goods carriers.

4. Guidance Sources for Transport of Biological Materials

There is detailed regulatory guidance and information on transport of dangerous goods and biological materials which is available from the Health and Safety Executive (HSE), Department for Transport (DFT), Department for Environment Food and Rural Affairs (DEFRA), Animal Health, Plant Health, Animal and Plant Health Agency (APHA), United Nations (UN), International Civil Aviation Organization (ICAO), International Air Transport Association (IATA) and World Health Organisation (WHO). Please see the links below to some important resources which provide information on the transport, import and export of biological materials.

4.1 Guidance

- HSE ACDP Management and operation of microbiological containment laboratories
- HSE ACDP Approved list of biological agents
- HSE Containment and control of specified animal pathogens
- WHO Guidance on the transport of infectious substances

4.2 Websites

- HSE Carriage of Dangerous Goods
- DFT Transporting Dangerous Goods
- DFT Shipping Dangerous Goods
- DFT Transport Security
- UK Import and Export
- IATA Dangerous Goods Regulations (DGR)
- ICAO Dangerous Goods
- UN Transport of Dangerous Goods
- Animal and Plant Health Agency
- Animal Health Import and Export (Scotland)
- Plant Health Import and Export (Scotland)

- Animal Health Import and Export (England)
- Plant Health Import and Export (England)
- Plant Health Licensing (Scotland)
- WHO Guidance on the transport of infectious substances

5. Classifying Biological Materials

The first step in transport of dangerous goods is the classification of the biological materials and infectious substances according to the regulations. The classification is used to determine the appropriate type of packaging, labelling, transporting and documentation requirements for the goods.

5.1 Dangerous Goods

Dangerous goods are defined as solid, liquid or gas substances or articles that have been classified according to an internationally agreed UN classification system. There are nine broad UN classes of dangerous goods in this system but there are also subdivisions within classes.

- Class 1 Explosives.
- Class 2 Gases.
- Class 3 Flammable liquids.
- Class 4 Flammable solids.
- Class 5 Oxidizers.
- Class 6 Toxic and infectious substances.
- Class 7 Radioactive materials.
- Class 8 Corrosives.
- Class 9 Miscellaneous.

Dangerous goods are assigned one or more of these UN class numbers and proper shipping names according to their hazard classification to clearly identify the dangerous article or substance. The proper shipping name and not the scientific or other names of the materials are important for the purposes of transport of dangerous goods including for biological materials and infectious substances. The UN numbers and proper shipping names are standardised across the world and recognised internationally as a detailed description of the goods. Each UN number and proper shipping name has an entry in the IATA Dangerous Goods List where the provisions that must be met when transporting the goods are indicated under the various columns. These include any limitations or special provisions that may apply, reference to the applicable numbered packing instruction that contains the detailed requirements for packaging the goods, and the labels that have to be affixed to the packages and any other requirements.

The UN approved classification under class 6 includes the specific classes of UN class 6.1 for toxic substances and UN class 6.2 for infectious substances. The classification scheme used for infectious substances in transport regulations reflects the risks associated with biological agents during transport rather than the risks to workers who could be exposed to biological agents in their work. For transport purposes an exposure is defined as occurring when an infectious substance is released outside of the protective packaging and resulting in physical contact with humans or animals.

The definitions and classifications of different types of biological materials for transport purposes are briefly summarised in the following sections but can be quite complicated. It is important to get the classification correct as this determines how the goods should be packaged and labelled and other transport requirements. Some biological materials are transported in chemicals or refrigerants which have hazardous properties and will be subject to specific controls under the transport regulations. The animal health and plant health regulators may have specific or additional requirements for the safe transport of specified animal pathogens or plant pathogens and pests.

5.2 Biological Materials and Infectious Substances

Biological materials that are hazardous due to an infection risk are allocated to UN class 6.2 infectious substances. Infectious substances are defined as substances which are known or are reasonably expected to contain pathogens which can cause disease in humans or animals. Pathogens are defined as microorganisms including bacteria, viruses, rickettsia, parasites, fungi and other agents such as prions which can cause disease in humans or animals. A wide variety of different types of biological materials may fall under the classification of infectious substances for the purposes of transport including microorganisms, infected materials, cultures, bodies, tissues, cells, samples, genetically modified microorganisms, biological products, and biological wastes. Infectious substances in class 6.2 are assigned to specific UN numbers with the corresponding proper shipping names. The UN description for class 6.2 divides infectious substances into either category A or category B and this forms the basis for determining which of the UN numbers should be assigned. Biological materials and infectious substances are placed in the following broad categories for the purposes of this guidance.

- Category A infectious substances.
- Category B biological substances.
- Genetically modified organisms.
- Biological materials and samples.
- Infected animals and plants.
- Biological products.
- Exemptions.
- Biological materials with chemicals or refrigerants.
- Biological wastes.

The categorisation of microorganisms into either category A or category B for transport purposes is not directly related to the hazard group classifications assigned under health and safety or environmental laws. Biological materials may have other hazardous properties such as toxicity and samples may be in chemicals or refrigerants. Remember that all of the hazardous properties must be taken into account during the classification of biological materials and related substances. If

more than one hazard is present then the classification depends on the nature of the different hazards and is determined by following rules on the order of precedence.

5.3 Category A Infectious Substance

Infectious substances are included in category A if they are capable of causing permanent disability, life threatening or fatal disease to exposed but otherwise healthy humans or animals. Category A infectious substances are assigned to the following UN numbers with the corresponding proper shipping name.

- UN 2814 INFECTIOUS SUBSTANCE, AFFECTING HUMANS
- UN 2900 INFECTIOUS SUBSTANCE, AFFECTING ANIMALS

Infectious substances meeting these criteria which cause disease in humans or both humans and animals must be assigned to UN 2814. Infectious substances which cause disease only in animals must be assigned to UN 2900. There is no comprehensive list of category A infectious substances. However there is an indicative list with examples of infectious substances that meet the criteria for assignment to category A which is given in the transport regulations and guidance. The category A indicative list includes hazard group 4 pathogens, hazard group 3 pathogens and some hazard group 2 pathogens. It is important to note that the list of indicative infectious substances is not exhaustive. Infectious substances including existing designated pathogens, new or emerging pathogens which do not appear in the indicative list but which meet the relevant criteria must be assigned to category A. In addition if there is doubt about whether or not a substance meets the criteria then it must be assigned to category A. Assignment to UN 2814 or UN 2900 must be based on relevant evidence, the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement concerning individual circumstances of the source human or animal.

5.4 Category B Infectious Substance

Infectious substances are included in category B if they are capable of causing disease to exposed but otherwise healthy humans or animals but which do not meet the criteria for inclusion in category A. Category B infectious substances are assigned to the following UN number with the corresponding proper shipping name.

- UN 3373 BIOLOGICAL SUBSTANCE, CATEGORY B

Infectious substances meeting these criteria which cause disease in humans or in both humans and animals must be assigned to UN 3373. Assignment to UN 3373 must be based on relevant evidence, the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement concerning individual circumstances of the source human or animal. Biological materials which have a potential infectious risk but are not in category A should be

assigned into category B and should not be assigned into the exempt category except in very limited circumstances.

5.5 Genetically Modified Organisms

Genetically modified organisms (GMO) which includes genetically modified microorganisms (GMM) must be classified as category A or B if they are infectious substances. The genetically modified organisms should first be assessed to determine if it is capable of causing disease in humans or animals then it should be classified as category A or B as appropriate. Genetically modified organisms which are category A or B infectious substances are assigned to one of the following UN number with the corresponding proper shipping name.

- UN 2814 INFECTIOUS SUBSTANCE, AFFECTING HUMANS
- UN 2900 INFECTIOUS SUBSTANCE, AFFECTING ANIMALS
- UN 3373 BIOLOGICAL SUBSTANCE, CATEGORY B

Genetically modified organisms that are infectious substances meeting the category A criteria which cause disease in humans or both humans and animals must be assigned to UN 2814. Genetically modified organisms that are infectious substances meeting the category A criteria which cause disease only in animals must be assigned to UN 2900. Genetically modified organisms that are infectious substances meeting the category B criteria which cause disease in humans or both humans and animals must be assigned to UN 3373.

Genetically modified organisms that are not infectious substances may still be hazardous because of other relevant characteristics. If the genetically modified organism or microorganism is not toxic or infectious for humans or animals but is still able to alter animals, plants or other microorganisms then it must be classified for transport purposes as UN class 9 miscellaneous dangerous goods. Genetically modified organisms meeting these criteria are assigned to the following UN number with the corresponding proper shipping name.

- UN 3245 GENETICALLY MODIFIED ORGANISMS
- UN 3245 GENETICALLY MODIFIED MICROORGANISMS

Genetically modified organisms or genetically modified microorganisms meeting these criteria must be assigned to UN 3245. Class 2, 3 or 4 genetically modified microorganisms requiring containment level 2, 3 or 4 based on the GM risk assessment because they are harmful or potentially harmful to humans or the environment are likely to be dangerous goods. Class 1 genetically modified microorganisms requiring containment level 1 based on the GM risk assessment because they are not harmful or potentially harmful to humans or the environment are not likely to be dangerous goods unless they have other relevant hazardous characteristics. Larger genetically modified organisms that are not microorganisms such as GM animals and GM plants and which are known or suspected to be

dangerous to humans or the environment are classified as dangerous goods in class 9 and should be assigned to UN 3245. These larger genetically modified organisms must also be transported in accordance with any additional conditions where required by the competent authority.

Genetically modified microorganisms which do not meet the definition of a toxic or infectious substance or have other relevant hazardous characteristics are not dangerous goods or subject to the provisions of the transport regulations. Genetically modified organisms that are not infectious and not able to alter animals, plants or microorganisms are not considered hazardous for transport but they should be properly packaged so they do not leak during transport and also be appropriately labelled so as to not to give rise to safety or security concerns of the material. Generally plasmids and nucleic acids are not dangerous goods and not controlled under the transport regulations unless they are toxic or infectious substances. However pathogenic virus vectors or virus infectious clones even if they are only the nucleic acids must be classified as infectious substances.

Some genetically modified organisms or genetically modified microorganisms are authorised for use in certain countries by the competent authority for that country. Where they have been so authorised, licensed or have consent for deliberate release into the environment, then they may not be subject to controls under the transport regulations providing that for any journey, authorisations apply in the country of origin, transit and destination. The School Biological Safety Adviser and University Biological Safety Adviser must be informed usually through the risk assessment process of any intention to import or export any class 3 genetically modified microorganism since advance notification must be made to the HSE.

5.6 Biological Materials and Samples

Biological materials and samples which are known or likely to contain pathogenic microorganisms should be classified as category A or B depending on whether it meets the criteria for infectious substances. Biological materials and samples from human or animals should be assigned to category A or B based on the known medical history and symptoms of the source human or animal, local conditions or professional judgement concerning individual circumstances of the human or animal sources. Cultures of pathogenic microorganisms that are infectious for humans or animals must be classified as category A infectious substance if they meet the relevant criteria or be classified as category B infectious substance if the they meet the relevant criteria. There is an increased risk of infection when exposure to the high concentrations of cultures of pathogens. Cultures are defined for transport purposes as resulting from a process by which the pathogens are intentionally propagated. Clinical materials sourced from humans or animals including bodies, body parts, organs, tissues, blood, body fluids and other materials being transported for research, teaching or diagnostic purposes should be assigned to category A or B depending on the clinical assessment or source of the material. Most clinical material should be classified as category B infectious substances unless it is known or

reasonably believed that the material contains category A infectious substances. Cultures of microorganisms that are not infectious for humans or animals are not subject to control under the transport regulations but they must be packaged in such a way that they are unlikely to leak in transport. Environmental materials that have hazardous properties which meet relevant criteria and pose a significant risk to humans or the environment will be dangerous goods.

Biological materials and samples which are unlikely to contain any infectious substances and which are not considered to pose a significant risk of infection are not subject to control under the transport regulations unless they meet the criteria for inclusion in another class. The nature and risks of the source material must be considered for the assignment of these materials as dangerous or non-dangerous goods. Biological materials such as DNA, RNA, plasmids, proteins or antibodies are generally not considered hazardous for transport unless they contain relevant hazardous substances but should be properly packaged so they do not leak during transport. Biological and clinical waste generated by the University is transported for disposal by an external contractor in compliance with the relevant transport and waste regulations. Please note that many biological materials may also be subject to import or export controls in addition to the national and international carriage of dangerous goods regulations.

5.7 Infected Animals and Plants

Live animals or plants must not be used to consign infectious substances or genetically modified microorganisms unless such substances cannot be consigned by any other means. There are also controls on the transport of infected carcasses. The transport of infected live animals or plants must be under terms and conditions or licences approved by the relevant competent authority. Infected live animals must not be transported by air unless specifically exempted. Schools wishing to transport live animals, animal carcasses or plants that have been intentionally infected must obtain permission from the relevant regulators.

5.8 Biological Products

Schools may have a requirement to transport biological products. Biological products are defined for transport purposes as those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals or for related development, experimental or investigational purposes. Biological products include materials like medical products and vaccines which are approved or licenced for use by the competent authorities. Some licensed biological products may still present a hazard but only in certain parts of the world. The competent authorities may in such cases require these biological products to be transported in compliance with local requirements for infectious substances or may impose other restrictions. Biological products that do not fall under the relevant

classification and which are known or reasonably believed to contain infectious substances must be classified as appropriate to Category A or Category B or other relevant Category and assigned to UN 2814, UN 2900, UN 3373 or UN 3245.

5.9 Exemptions

Biological materials and substances which do not contain infectious substances and are unlikely to cause disease in humans or animals are not dangerous goods unless they have other hazardous properties which meet the criteria for inclusion in another class. Biological materials where there is minimal likelihood that pathogens are present are exempt from the regulations provided they are packaged in a way so as to prevent leakage during transport and labelled with the corresponding proper shipping name.

- UN EXEMPT HUMAN SPECIMEN
- UN EXEMPT ANIMAL SPECIMEN

Exempt biological materials and substances include non-pathogenic microorganisms, biological materials used for therapeutic and diagnostic tests, organs or tissues blood or blood components used for transplantation and substances for which there is a low probability that infectious substances are present, or where the concentration of pathogens is at a level naturally encountered and which are not considered to pose a significant risk of infection. Environmental materials and samples which do not pose a significant risk to humans or the environment are not considered dangerous goods unless they meet the criteria for inclusion in another class. The nature and individual circumstances of the source material must be considered for the assignment of materials as dangerous or non-dangerous goods. Biological materials that have been decontaminated or treated to inactivate any infectious substances that may be present using properly validated procedures such that they no longer pose a risk to health are not subject to control under the various transport regulations with the exception of wastes.

Professional judgement must be used to determine the likelihood of pathogens or other hazards being present in the materials and samples and whether it is appropriate to transport materials and samples as exempt human or animal specimens. The judgement should be based on any relevant evidence including known medical history, symptoms and individual circumstances of the source human or animal, and endemic local conditions or the presence of infectious diseases in the source population. Biological materials or samples collected from humans, animals, plants or the environment and which are known or likely to contain pathogens are considered as a minimum to be category B infectious substances. These may not be transported as exempt specimens.

5.10 Biological Materials with Chemicals or Refrigerants

Biological materials and samples are often transported with chemicals which are usually used as preservatives or with refrigerants to maintain low temperatures and these are classified as dangerous goods. The chemicals or refrigerants must be classified for transport purposes according to the hazardous properties which meet the criteria for inclusion in another class and this is in addition to the classification for the biological materials. If the biological materials are packaged with solid carbon dioxide (dry ice) then this must be additionally classified for transport purposes as UN class 9 miscellaneous dangerous goods. The carbon dioxide refrigerant is assigned to the following UN numbers with the corresponding proper shipping name.

- UN 1845 DRY ICE
- UN 1845 CARBON DIOXIDE, SOLID

The carbon dioxide dry ice refrigerant using either of these proper shipping names must be assigned to UN 1845. If the biological materials are packaged with liquid nitrogen then this must be classified for transport purposes to the appropriate UN number with the corresponding proper shipping name. The use of liquid nitrogen should be avoided wherever possible for refrigerating infectious substances during transport. There is specialised UN type approved packing required to transport infectious substances in liquid nitrogen. Schools should consign biological materials or infectious substances in liquid nitrogen only if there is no suitable alternative means and should contact the DGSA for further advice on the particular consignment requirements.

Biological materials may be transported with chemicals and be subject to controls under the transport regulations. The transport of samples containing chemicals which have hazardous properties must meet the necessary transport requirements for the chemical and be assigned to the relevant UN number and proper shipping name. The transport requirements will vary depending not only on the chemical but also on the classification of the biological materials due to infectious properties and the mode of transport so specific advice may need to be obtained. Guidance on transporting chemicals is not included here and a DGSA should be contacted where needed for further advice on particular consignment requirements.

5.11 Biological Wastes

Biological wastes are subject to control under the transport and waste regulations. Waste derived from the medical treatment of humans or animals or from bioresearch are termed clinical or medical wastes and are assigned to one of the following UN number with the corresponding proper shipping name.

- UN 3291 CLINICAL WASTE, UNSPECIFIED, N.O.S.
- UN 3291 (BIO) MEDICAL WASTE, N.O.S.

- UN 3291 REGULATED MEDICAL WASTE

Biological wastes are assigned to UN 3291 unless they have other hazardous properties and are assigned to the relevant UN number with the corresponding proper shipping name. Information on waste classification, packaging, labelling or transport provisions is not included in this guidance and can be obtained from the Waste and Recycling Service.

6. Packaging and Labelling Biological Materials

Dangerous goods and biological materials must be safely packaged and labelled to contain and prevent accidental exposure or release of substances during transport to protect people and the environment. The transport regulations and guidance set packaging and labelling requirements which must be used and depend on the classification of the materials to be transported. These requirements are detailed in specific applicable packing instructions (PI) which are individually numbered as referenced in the Dangerous Goods List against each UN number and proper shipping name.

A brief summary of the packaging and labelling requirements is given below but only for the main biological materials and infectious substances. The full details can be found in the transport regulations and guidance including differences for the different modes of transport. The packaging requirements are essentially identical whether the goods are transported by road or air apart from restrictions on the quantity of materials in packages for air transport. However it is important to obtain competent advice from your School Biological Materials Transport Adviser where needed in relation to the packaging, labelling and transporting of dangerous goods and if necessary for complex issues from a DGSA.

6.1 Packaging Systems

Biological materials and infectious substances must be packaged using appropriate UN transport packaging systems. The packages must have the relevant hazard labels, UN numbers and proper shipping names and have the relevant shipping documentation and contact details. Biological materials must be contained in suitable robust and leak proof primary containers which must be placed inside a robust and leak proof container so that they do not leak during transport and then placed inside an outer package. Multiple packages may be placed into overpacks. Infectious substances must be packed using a UN triple packaging container system. Non-hazardous biological materials may require only a single or double packaging containers.

Packaging must have the appropriate markings and labels on the outer container for the relevant classes of dangerous goods. Labels must be durable and legible and clearly visible on the outside of the packaging. The package must be of such a size that there is adequate space to fix all the required markings and labels. Labels must

be located on the same surface of the package affixed adjacent to the consignor's or consignee's address and must not be folded or affixed in such a manner that the same label appears on different faces of the package. The package must be of such a size that there is adequate space to affix all required labels.

Packages should be clearly labelled with the delivery address and senders details. Emergency contact details should be shown on outer packages and include a named persons at both consignee and consignor organisations and telephone numbers. It is recommended that emergency contact details are shown on all packages containing biological materials irrespective of whether they are required in the regulations in order to facilitate dealing with any issues during transport.

6.2 Triple Packaging Systems

The UN approved triple packaging container system is used for infectious substances and consists of three layers as follows including a primary container, absorbent material, secondary container and an outer container with the relevant labels and markings.

- **Primary container**: Robust, watertight and leak proof packaging with seal containing the infectious substance. The primary container should be packaged with enough absorbent material around it to absorb all fluid in case of breakage.
- **Secondary container**: Robust, watertight and leak proof packaging with seal to enclose and protect the primary container. Several cushioned primary receptacles can be placed in one secondary packaging but sufficient absorbent material should be used to absorb all fluid in case of breakage.
- **Outer container**: Robust outer container with suitable cushioning material to enclose and protect the secondary container. The outer packaging should protect contents from physical damage during transport and has the relevant labels and markings.

The diagram below is an example of the types of packaging systems available for biological materials and infectious substances.

6.3 Single and Double Packaging Systems

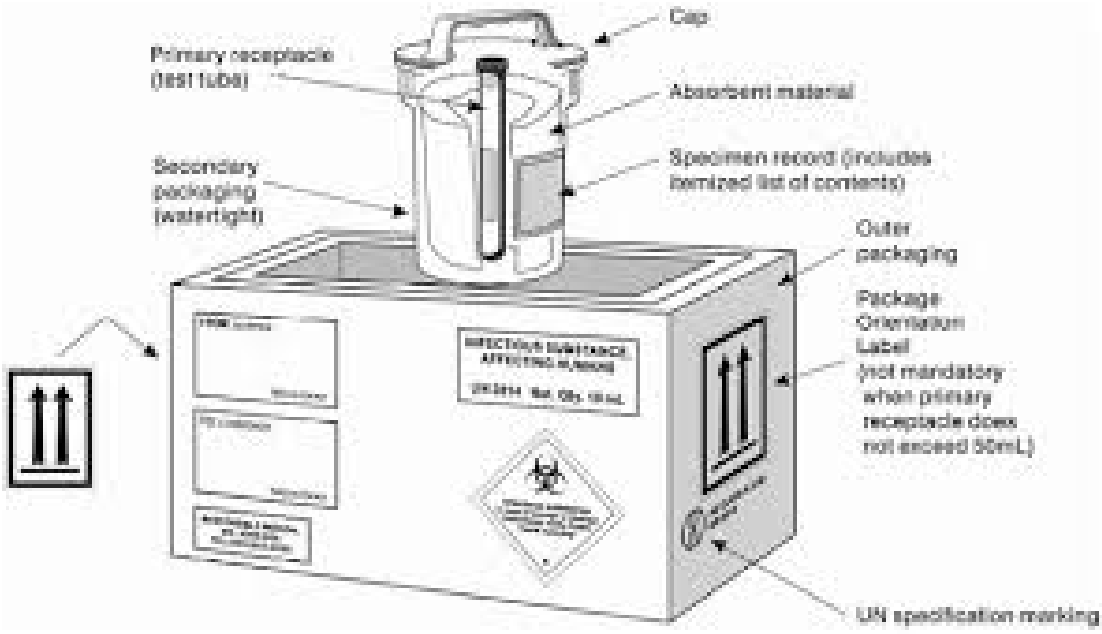
Biological materials which are not hazardous or infectious substances may require only a single or double packaging containers. There are many types of packaging systems which are available can be used or for biological materials.

6.4 Overpacks

Several dangerous goods packages may be carried inside a single overpack. An overpack is an enclosure used by a shipper to contain one or more packages in one convenient handling unit. Each package enclosed within an overpack must be properly packed, marked and labelled. The overpack must have all the relevant markings and labels that are on the packages it contains reproduced on the outside of the overpack.

6.5 Packaging and Labelling Requirements for Category A Infectious Substances Assigned to UN 2814 or UN 2900

Category A infectious substances harmful to humans or animals assigned to either UN 2814 or UN 2900 must be packed in accordance with ADR packing instruction PI 620 for road transport or IATA packing instruction PI 602 for air transport. Typical packaging and labelling for category A infectious substances is shown in the following diagram. Packaging for category A infectious substances must meet UN performance requirements shown by design type testing and be specifically approved for class 6.2 substances. These are known as UN type approved packaging and they are certified and marked accordingly.



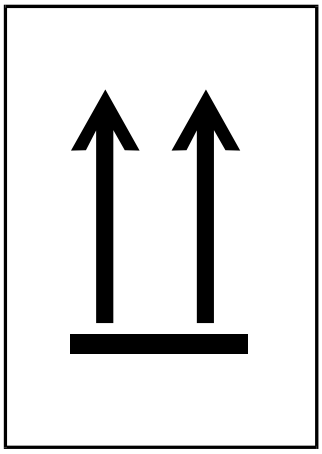
The package must be marked with one of the following UN numbers and proper shipping names.

UN 2814 INFECTIOUS SUBSTANCE, AFFECTING HUMANS

UN 2900 INFECTIOUS SUBSTANCE, AFFECTING ANIMALS only

The hazard warning label for category A infectious substances shown below must be affixed to the package. Note that for category A infectious substances the label contains the dangerous goods class number 6 and biohazard sign.

The scientific or technical name of the microorganism must not appear on the package but should be supplied in the accompanying transport documentation. Emergency contact details including name and telephone number must be shown on outer packages containing category A infectious substances. Packages containing liquids must display suitable package orientation labels. The labels must be affixed or pre-printed on at least two opposite sides to show the proper orientation for the primary containers to be in the upright position. Note that orientation arrows are not required on packages containing class 6.2 infectious substances in primary receptacles of not more than 50ml although they may be used.



Packages suitable for cargo aircraft only since there are quantity restrictions which apply on passenger aircraft. The Cargo Aircraft Only label must be used if the package is permitted only on cargo aircraft where it contains more than the quantity allowed on a passenger aircraft. The Cargo Aircraft Only label must be affixed on the same surface of the package as the hazard label.

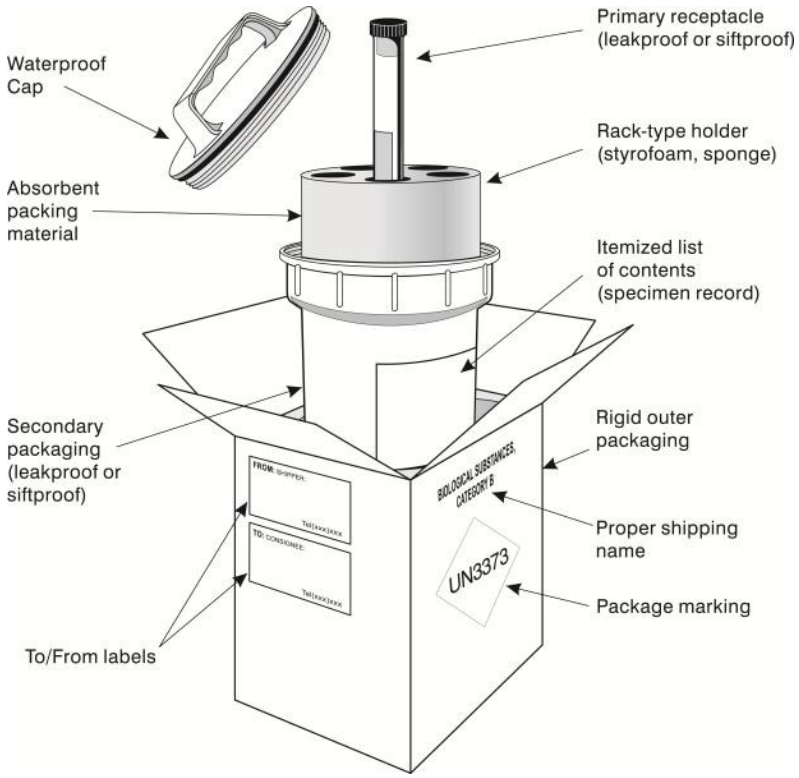
There are no limits on the quantity of materials contained within either a primary container or the total package for road transport. This is in contrast to air transport where there is a 50ml/50g limit for each package on passenger aircraft and a 4l/4kg limit for each package on cargo aircraft. There is an exception to this rule in air transport for body parts, organs or whole bodies. If an overpack is used to contain several packages then it must be marked with the following name.

OVERPACK

The markings and labels which are on the packages that it contains must also be repeated on the outside of the overpack.

6.6 Packaging and Labelling Requirements for Category B Infectious Substances Assigned to UN 3373

Category B infectious substances harmful to humans or animals assigned to UN 3373 must be packed in accordance with ADR packing instruction PI 650 for road transport and IATA packing instruction PI 650 for air transport. Typical packaging and labelling for category B infectious substances is shown in the following diagram. Packaging for category B infectious substances must meet PI 650 requirements but do not have to be UN approved.



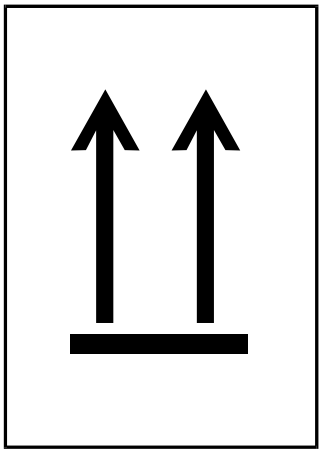
The package must be marked with the following UN number and proper shipping name.

UN 3373 BIOLOGICAL SUBSTANCE, CATEGORY B

The hazard warning label for category B infectious substances shown below must be affixed to the package. Note that for category B infectious substances the label does not contain either the dangerous goods class number 6 or biohazard sign.

The scientific or technical name of the microorganism must not appear on the package but should be supplied in the accompanying transport documentation.

Packages containing liquids must display suitable package orientation labels. The labels must be affixed or pre-printed on at least two opposite sides to show the proper orientation for the primary containers to be in the upright position. Note that orientation arrows are not required on packages containing class 6.2 infectious substances in primary receptacles of not more than 50ml although they may be used.



Packages suitable for cargo aircraft only since there are quantity restrictions which apply on passenger aircraft. The Cargo Aircraft Only label must be used if the package is permitted only on cargo aircraft where it contains more than the quantity allowed on a passenger aircraft. The Cargo Aircraft Only label must be affixed on the same surface of the package as the hazard label.

There are no limits on the quantity of materials contained within either a primary container or the total package for road transport. This is in contrast to air transport on both passenger and cargo aircraft where primary containers must not exceed 1 litre and packages must not contain more than 4 litres for liquids, and outer packaging must not contain more than 4Kg for solids. There is an exception to this rule in air transport for body parts, organs or whole bodies. If an overpack is used to contain several packages then it must be marked with the following name.

OVERPACK

The markings and labels which are on the packages that it contains must also be repeated on the outside of the overpack.

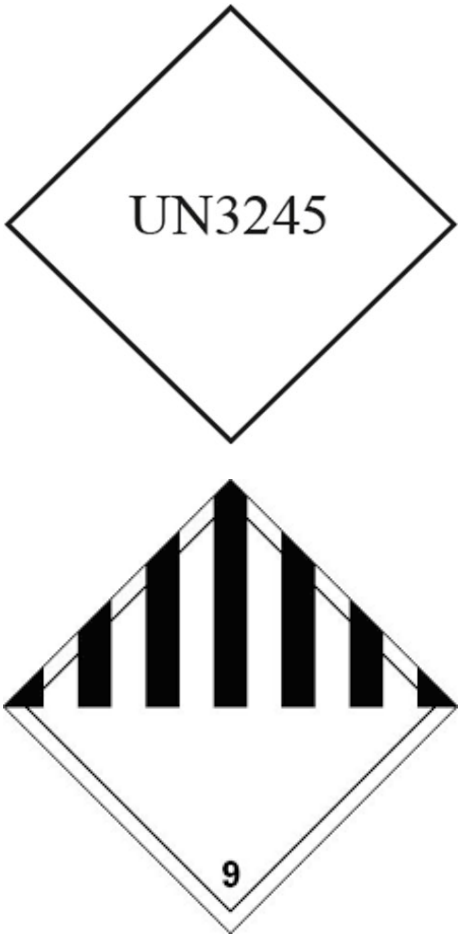
6.7 Packaging and Labelling Requirements for Genetically Modified Organisms Assigned to UN 3245

Genetically modified organisms assigned to UN 3245 must be packed in accordance with ADR packing instruction PI 904 for road transport and IATA packing instruction PI 959 for air transport. The package must be marked with one of the following UN numbers and proper shipping names.

UN 3245 GENETICALLY MODIFIED ORGANISMS

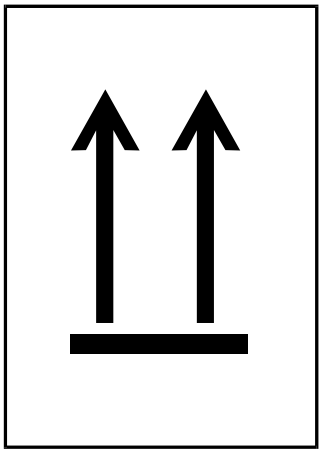
UN 3245 GENETICALLY MODIFIED MICROORGANISMS

Note that this applies only to genetically modified organisms assigned to UN 3245. Genetically modified microorganisms assigned to UN 2814, UN 2900 or UN 3373 must be packaged and labelled as category A or B infectious substances. The hazard warning labels for genetically modified organisms shown below must be affixed to the package. The miscellaneous hazard label contains the dangerous goods class number 9.



The scientific or technical name of the microorganism must not appear on the package but should be supplied in the accompanying transport documentation.

Packages containing liquids must display suitable package orientation labels. The labels must be affixed or pre-printed on at least two opposite sides to show the proper orientation for the primary containers to be in the upright position. Note that orientation arrows are not required on packages containing class 6.2 infectious substances in primary receptacles of not more than 50ml although they may be used.



Packages suitable for cargo aircraft only since there are quantity restrictions which apply on passenger aircraft. The Cargo Aircraft Only label must be used if the package is permitted only on cargo aircraft where it contains more than the quantity allowed on a passenger aircraft. The Cargo Aircraft Only label must be affixed on the same surface of the package as the hazard label.

There are no limits on the quantity of materials contained within either a primary container or the total package for road or air transport. If an overpack is used to contain several packages then it must be marked with the following name.

OVERPACK

The markings and labels which are on the packages that it contains must also be repeated on the outside of the overpack.

6.8 Packaging and Labelling Requirements for Exempt Human or Animal Specimens

Exempt human or animal specimens must be packed in accordance with the packing requirements detailed in the ADR and IATA transport regulations and guidance rather than within a numbered packing instruction and must be followed for any specimen transported under the exemption. The package must be marked with one of the following UN numbers and proper shipping names.

UN EXEMPT HUMAN SPECIMEN

UN EXEMPT ANIMAL SPECIMEN

Biological materials where there is minimal likelihood that pathogens are present are exempt from the transport regulations provided they are packaged in a way so as to prevent leakage during transport and labelled with the corresponding proper shipping name. There are no limits on the quantity of materials contained within either a primary container or the total package for road or air transport.

6.9 Packaging and Labelling Requirements for Non-Hazardous Biological Materials

Biological materials that are not hazardous or infectious are not classified as dangerous goods or subject to control under the transport regulations. There are no labelling requirements for biological materials that are not classified as dangerous goods but they must still be packaged in such a way that they do not leak during transport. Non-hazardous biological materials should be transported in the appropriate containers and packaging systems. Genetically modified organisms and most plasmids and nucleic acids that are not infectious and not able to alter animals, plants or microorganisms which are not classified as dangerous goods or hazardous for transport but should be properly packaged so they do not leak during transport. The packages should be appropriately labelled so as to not to give rise to safety or security concerns of the material.

Note that the transport of biological materials, microorganisms, genetically modified organisms, animals or plants may require licences and authorisations from the competent authorities in the UK or other governments and they may require specific agreed transport methods to be used to transport them nationally or internationally even if they are not dangerous goods or subject to the transport regulations. Biological products which are licenced and authorised for use in certain countries by the competent authority for that country may be still require authorisation and licensing in other countries.

6.10 Packaging and Labelling Requirements for Refrigerated Materials and Chemicals

Biological materials and infectious substances are often transported with chemicals or refrigerants which are used to stabilize or preserve them during the journey. Note that other dangerous goods must not be put into the same packaging as class 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. Chemicals used for transport may be hazardous such as flammable, corrosive or toxic as defined under the dangerous goods regulations and will require appropriate packing, marking and labelling. There are exceptions for very small quantities of certain chemical preservatives for category A or B infectious substances which mean that there are no additional requirements of the ADR or IATA regulations. The full details of how to use chemicals or refrigerants like dry ice or liquid nitrogen including the relevant packaging, hazard labelling, marking and documentation required are given in the transport regulations and guidance. Biological materials are frequently transported at low temperatures either on wet ice or dry ice and particular care must be taken to ensure the integrity of the packaging used is not compromised when these melt or dissipate. Great care is required in the use of refrigerants because of the risk of explosion if they are incorrectly used or packaged.

Dry ice or solid carbon dioxide is assigned to UN 1845. There is no applicable packing instruction for road transport of dry ice but it must be packed in accordance with IATA packing instruction PI 904 for air transport. The package must be marked with one of the following words where the package contains dry ice and is transported by road.

DRY ICE

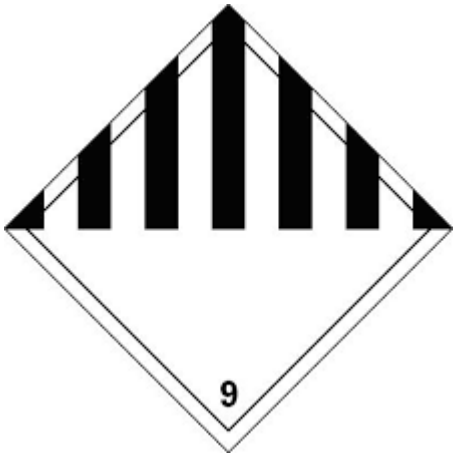
CARBON DIOXIDE, SOLID

The UN number and associated hazard label are not required. The package must be marked with one of the following UN numbers and proper shipping names where the package contains dry ice and is transported by air. Mark the package with the net weight of dry ice

UN 1845 DRY ICE ## kg

UN 1845 CARBON DIOXIDE, SOLID ## kg

The hazard warning label for dry ice shown below must be affixed to the package. Note that the miscellaneous hazard label contains the dangerous goods class number 9.



Dry ice must be placed only in packaging designed and constructed to permit the release of carbon dioxide gas and to prevent an increase of pressure that could rupture the packaging. If dry ice is used to cool the materials it must be placed around the secondary container. The outer packaging and any overpack must permit the release of carbon dioxide gas. Dry ice must never be placed inside either the primary or secondary container as gas will build up and eventually these will explode with potential to cause very serious damage. If wet ice is used it should be placed around the secondary packaging in the form of sealed cold packs or similar rather than being loose and the outer packaging should be leakproof. The primary container and the secondary container need to be able to maintain their integrity at the temperature of the refrigerant used.

If an overpack is used to contain several packages then it must be marked with the relevant markings and labels which are on the packages that it contains must also be repeated on the outside of the overpack. The final packaging combination must meet UN performance requirements where these are used for packages containing category A infectious substances. UN type approved packaging systems, insulated overpacks and thermal control packaging systems which are specifically designed for use with wet ice or dry ice are available commercially. There are particularly stringent requirements for road or air transport of infectious substances in liquid nitrogen. There are special shipping containers for transporting infectious substances in liquid nitrogen. Schools should not consign infectious substances in liquid nitrogen unless there is no suitable alternative and then advice on the particular consignment requirements should be obtained from a Dangerous Goods Safety Adviser.

6.11 Suppliers of Dangerous Goods Packaging Products

Dangerous goods packaging systems and containers for transporting biological materials and infectious substances can be obtained from various suppliers. The following companies for example supply a range of dangerous goods packaging systems and containers for carriage of biological materials, category A and category B infectious substances or transport bags.

- Air Sea Containers
- SafTPak
- Intelsius
- Versapak
- Royal Mail Safebox
- Labeline

Note that there is no specified packaging for non-hazardous biological materials but safe and suitable robust and leak proof containers and packaging materials are still required.

6.12 Biological Materials Transport Bags

Biological material transport bags can be used to carry many types of biological materials and samples. There are excellent commercially available UN 3373 PI 650 approved transport bags for carrying biological materials which can be useful for many purposes including for example of samples between campuses and from hospitals to the university or during fieldwork. Biological material transport bags must be suitably robust, sealable and have the relevant hazard labels and markings on the outside (UN 3373) and they are often insulated to maintain low temperatures and may have external document pouches. Typical examples of biological material transport bags are shown below for information.

6.13 Royal Mail Safebox

The Royal Mail produces a packaging system called Safebox which can be used for sending small quantities of category B infectious substances assigned to UN 3373 in the domestic mail postal system. Safebox is not UN type approved for category A infectious substances and must not be used for these materials. Note that category A and category B infectious substances are not permitted in international mail to or from the UK. Safebox comes as a complete ready to use kit including pre-paid postage and packages can be directly posted using a pillar box.

Safebox is only available through Royal Mail and further details are available on their website.

7 Transporting Biological Materials

Biological materials and infectious substances must be safely and securely transported between the sender, carrier and receiver to prevent the exposure of people or release into the environment. Biological materials need to be transported between buildings on site and university campuses as well as nationally and internationally. The controls required for transporting biological materials depend on the nature of the dangerous goods and may involve using local transport, postal services or dangerous goods carriers. The detailed transport requirements can be found in the relevant regulations and guidance and advice can be obtained from your School Biological Materials Transport Adviser and the dangerous goods carriers and their Dangerous Goods Safety Advisers.

7.1 Internal Transport of Biological Materials

Biological materials must be appropriately packaged and safely transported between buildings and local sites in the immediate vicinity. The transport regulations apply where dangerous goods are transported by any means on the public highway. However there is a general exception where they do not apply to transport between buildings on a university campus or other premises situated in the immediate vicinity even if they are separated by a public road. However even where the regulations do not apply the materials must still be safely packed to ensure they do not leak in transit and be appropriately labelled with emergency contact details. You will need to use suitable packaging containers for the materials with correct hazard warning signs and the relevant information where needed. In some cases you may need to take safety information, PPE and a spill kit in case of an accident. Biological materials must be transported by trained and competent workers. If you are transporting the biological materials then the containers must bear the appropriate signage with emergency contact information including contact names and telephone numbers. In the event of an incident during transport then this signage will identify a member of university staff who can be contacted for safe collection of the biological materials. Remember that you must ensure that all the relevant safety as well as transport requirements and controls are in place for all the hazards involved in transporting the biological materials including any chemicals and refrigerants. The classification, packaging and labelling requirements must be met irrespective of the means of transport.

7.2 External Transport of Biological Materials

Biological materials must be appropriately classified, packaged, labelled and safely and securely transported. The transport methods required will depend on the specific types of dangerous goods, transport mode, route and destination. Biological materials must be transported by trained competent workers or by general carriers or dangerous goods carriers. Please note that you must never carry any kind of dangerous goods on your person or in cabin or checked baggage when using air

transport or when travelling between different countries when using any mode of transport. Many biological materials require a licence before they are transported into or out of the university, around the country or overseas. High consequence dangerous goods (HCDG) such as category A infectious substances must only be transported using suitable dangerous goods carriers.

7.3 Dangerous Goods Carriers

Dangerous goods carriers are companies which provide national or international transport of dangerous goods. They provide various services and so it is important to establish that the carrier is able to handle the relevant dangerous goods and any other requirements. Dangerous goods carriers must comply with all the carriage of dangerous goods regulations and use fully compliant vehicles with all the relevant safety, security and transport regulations including having the required equipment, hazard warning signs, safety information, competent trained and certified drivers and the necessary emergency equipment and arrangements. There are a number of dangerous goods carriers which specialise in biological materials and infectious substances.

Dangerous goods carriers will provide guidance on all aspects of the transport process and their transport coordinators and Dangerous Goods Safety Advisers should be able to give specific advice on any complex issues. The carrier will explain their packaging requirements and will supply the relevant transport documentation for completion and the necessary instructions for the relevant transport routes. They may ask for additional documentation to meet their own internal safety requirements. You need to ensure that you comply with the correct classification, packaging, labelling and documentation which are required by the relevant regulations as well as by the carrier for your biological materials. You must give a full description of the goods to the carrier company when arranging the shipment including the UN number and proper shipping name. Carriers must always be told if the package contains dry ice even if only non-dangerous goods are being transported. Note that carriers may refuse to handle dangerous goods where there are any concerns. You must ensure you have completed any relevant import or export documentation and obtain any relevant licences that may be required. Please note that the university has approved dangerous goods carriers which provide a service to transport dangerous goods.

7.4 Transport by Road

Category A infectious substances assigned to UN 2814 or 2900 must be transported using specialist dangerous goods carriers with the appropriate licences and never by university workers in private vehicles, university vehicles or on public transport. Category A infectious substances must be carried in fully compliant vehicles with all the required equipment, hazard warning signs, safety information and the necessary emergency equipment and arrangements and the driver must be trained and certified to carry dangerous goods.

Category B infectious substances assigned to UN 3373 can be transported using university vehicles or suitable private transport provided that they are correctly packaged, labelled and the relevant documentation is provided in accordance with all the relevant safety and transport regulations and guidance. The vehicle and driver must also have appropriate business insurance and licences. You may need to have various emergency arrangements in place with the necessary equipment like communication methods (eg mobile phone), emergency contacts details, PPE and a suitable spill kit in case of an accident. Non-infectious biological materials can also be carried using university vehicles or suitable private transport provided that they are correctly packaged and safely transported. Biological material transport bags can be very useful for the transport by vehicle of many biological materials and samples such as between campuses and sites, from hospitals to the university or for fieldwork.

Public transport services may allow certain materials to be carried but you must check their specific regulations. Taxi services can with permission be used to transport biological materials including category B infectious substances but not category A infectious substances, provided that the materials are correctly packaged, labelled and contain relevant documentation in accordance with the regulations. Exempt human and animal specimens and dry ice which are packed and labelled in accordance with the requirements of the transport regulations are not subject to any of the other provisions of the regulations.

7.5 Transport by Air

The specialist dangerous goods carrier organises the shipments and make any necessary arrangements including any specific requirements for the consignment. The sender will need to complete the relevant documentation including an Air Waybill and where necessary a Shipper's Declaration for Dangerous Goods. Note that some countries and airlines place additional restrictions or constraints on certain shipments for air transport. For example some countries prohibit entry of infectious substances without prior approval by the authorities and some airlines will not carry infectious substances. These restrictions are included within the IATA regulations as state and operator variations. Many airlines require advance arrangements to be made for the transport of dangerous goods. The air transport regulations specify that dangerous goods such as category A and category B infectious substances must always be transported as separate packages in the hold and must always be declared. Dangerous goods must not be carried by passengers as or in checked baggage, carry-on baggage or on their person. The operator airline is required to report to the appropriate State authority when undeclared or misdeclared dangerous goods are discovered as this is a serious offence and would be dealt with accordingly by the authorities.

7.6 Postal Services

The postal services have strict controls on the transport of dangerous goods and these are set out in their service regulations. Certain types of dangerous goods cannot be sent by post at all whereas others are accepted only on a restricted basis subject to provisions specified by the national postal authorities. The Royal Mail refers to these types of items as prohibited and restricted goods respectively. Senders of letters and packages containing dangerous goods must always ensure they follow Royal Mail requirements prior to despatch of such materials in the postal services. Biological materials sent by the domestic postal services must be classified, packaged and labelled in accordance with the requirements set out in the relevant regulations. Biological materials sent by postal services should also be sent in accordance with air transport requirements since national post may be carried by air in the UK. Only recognised institutions, laboratories or certain professional persons are permitted to send hazardous biological materials in the post. Members of the public may only post such materials at the specific request of such a laboratory or person. If you are planning research that requires participants to send you biological materials then you should ensure that they use the appropriate packaging and transport mode to send you the samples. You must read the relevant service regulations on the transport of dangerous goods and biological materials on the postal company websites and contact them for advice where needed.

Biological materials which are classified as dangerous goods including any materials assigned to UN 2814, UN 2900, UN 3373 or UN 3245 cannot be sent in the international postal services either to or from the UK. Category A and B infectious substances cannot be sent overseas using ordinary postal services and you will need to use dangerous goods carriers. Category A infectious substances are prohibited in the domestic postal services. Category B infectious substances may be posted subject to any specific requirements of the postal services usually within defined package limits and provided they are packaged and labelled in accordance with the regulations. Genetically modified organisms classified as UN 3245 and exempt human or animal specimens can also be sent by some domestic postal services appropriately packaged and labelled. Dry ice is prohibited in the domestic post. The amount of infectious substances which includes any items assigned to UN 3373, UN 3245 or exempt human or animal specimens that can be sent by post is usually restricted to a maximum quantity of 50g or 50ml for each package.

In general living creatures cannot be sent by post. Schools should wherever possible avoid sending living creatures by post although some are accepted under certain conditions. Royal Mail may carrier certain living creatures but only by prior arrangement. They must be sent in boxes which prevent all risk of injury to their staff and damage to other items and must also be packaged so as not to cause death or distress to the creatures themselves. The transport of live infected animals or plants requires special controls and unless there is no alternative it is usually best to transport animals and plants separately from infectious agents. Live animals infected with serious human or animal pathogens should not be transported outside the

appropriate laboratory facilities. Live plants and plant materials infected with pathogens are generally more straightforward to transport as long as they are appropriately packaging and labelled. Specific advice or instructions must be taken from the competent authorities for the transport of infected animals or plants and relevant licences obtained where required.

7.7 Documentation

There are certain shipping documents that are required to be completed for transporting of packages containing dangerous goods including dangerous goods declaration forms, airway bills and shippers declaration for dangerous goods. The dangerous goods carriers will provide the relevant documents and forms for you to complete and provide advice where needed. There are requirements for paperwork to be included within the package and for paperwork accompanying the package for the carrier depending on the type of dangerous goods. The information must be clearly legible and must exactly meet the specified format required for the mode of transport. The paperwork within packages must be between the secondary and the outer layers, giving the names and addresses of both the consignor (sender) and consignee (receiver) including emergency contact details (name and telephone number) at both ends and a description of the dangerous goods including the UN number and proper shipping name and the scientific or technical name of the microorganism. When the infectious substances to be transported are unknown but suspected of meeting the criteria for inclusion in category A and assignment to UN 2814 or UN 2900 then the words "suspected category A infectious substance" in parentheses should be used as the technical name. An itemised list of contents must be given to include for each named item the number of tubes and their volume. You must always give a full description of the goods to the dangerous goods carrier company when you are initially arranging the shipment including the relevant UN numbers and proper shipping names to ensure they are aware that they will be transporting dangerous goods and the necessary paperwork is completed.

For transport by road of packages containing dangerous goods other than those assigned to UN 3373 as category B infectious substances, the carrier company transporting the goods should request that a dangerous goods declaration form be completed. Typically the carrier will provide a copy of the form for completion. For transport by air of packages containing dangerous goods it is necessary to complete an Air Waybill and in most cases a Shipper's Declaration for Dangerous Goods. For exempt human or animal specimens, a simple statement saying what are the materials and that there is minimal likelihood that pathogens are present and that they are exempted under the transport regulations. For non-hazardous biological materials, a simple statement describing the materials and that they are non-hazardous and that they are not classified as dangerous goods under the transport regulations. Written emergency response procedures must also be provided with any package containing biological materials classified under UN 2814, UN 2900, UN 3373 or UN 3245. The person receiving the materials is generally regarded as the importer and the one responsible for obtaining all the necessary appropriate authorisations, certifications

and licences. Biological materials requiring an import permit, licence or notification for import into the UK include all hazard group 4 and some hazard group 3 pathogens, materials covered by anti-terrorism legislation, animal pathogens, plant pathogens or pests and certain animals, plants or related materials.

7.8 Communications

It is essential to ensure that there are good communications between the senders and receivers and the relevant information is shared about any shipments of dangerous goods, biological materials and infectious substances. All consignments must be acceptable to the recipients and the dangerous goods or postal service carriers. You must communicate at all relevant stages the relevant details of shipments to recipients for packages that you are sending and senders must communicate the relevant details of shipments to you. The relevant details of shipments will include the senders contact details, description of the biological materials being sent, packaging system and the details of the carrier, delivery times and dates. This can be done using a variety of methods but it is recommended that written emails should be used in addition to other methods like the phone to communicate details in advance since these provide a reliable means of communicating and recording information. The delivery or non-delivery of shipments should also be confirmed with senders as appropriate to ensure that issues are followed up and the transport process is closed out when completed.

It is very important that the correct transport arrangements are agreed between all the relevant parties in advance to avoid any failures in compliance with the relevant regulations or issues arising during the chain of transport. If you are doing research work that requires other persons or organisations to send biological samples or other materials to the university or if you are sending biological samples or other materials to other persons or organisations then you should ensure that the appropriate packaging and transport mode will be used to send the samples. The person sending the goods (consignor) should contact the person to whom they are being sent (consignee) before sending or receiving any biological materials to let them know shipping details and to check that the substance may be legally sent or received and that all authorizations are in place before sending the materials.

7.9 Security

The transport regulations have security requirements which mean that controls must be in place to prevent the theft or misuse of dangerous goods at all points of the transport chain. The standard security arrangements requires dangerous goods carriers and postal service carriers to have vehicles, processes and arrangements fully compliant with the safety, security and transport regulations including having the relevant equipment, hazard warning signs, safety information, competent trained and certified drivers and emergency arrangements. Packages of infectious substances must be handed over only to appropriately identified persons and companies. Packages awaiting either external or internal collection following

delivery must be properly secured and not accessible to anyone except authorised persons.

There are higher risk biological materials which require additional internal and external security controls. These materials are called high consequence dangerous goods (HCDG) which includes category A infectious substances assigned to UN 2814 or UN 2900 and Schedule 5 designated pathogens and toxins controlled under anti-terrorism laws. High consequence dangerous goods are those which have the potential for misuse in a terrorist incident and which may as a result produce serious consequences such as mass casualties or mass destruction. They must only be transported using an approved dangerous goods carrier and there are are additional security controls that must be implemented for such goods. The transport of high consequence dangerous goods must comply with the relevant safety and security requirements including any local transport security plans and arrangements. The School Biological Materials Transport Adviser and University Biological Safety Adviser must be contacted in advance of any intention to transport any HCDG or pathogens, toxins or other related substances which are subject to controls under anti-terrorism legislation.

8. Importing and Exporting Biological Materials

There are rigorous licensing requirements for the import, export and possession of many types of biological materials and infectious substances. The possession or use of certain hazardous biological materials may also require permission to be obtained before they are brought into the university. There are various import and export requirements that may apply to national and international transport of biological agents, genetically modified organisms, animal pathogens, plant pathogens or pests and other biological materials. Schools should be aware that import, export and licence requirements may vary for different parts of the UK, EU and other countries. The importation of materials into some countries is particularly tightly regulated and there are many restrictions on dangerous and non-dangerous goods. Please note that it is not possible to state here all the relevant import or export requirements and which materials may require a licence since there are complex regulations involved and many types of licences and controls. There is detailed guidance on the regulations and requirements for import, export and licences which can be obtained from the UK Government, Scottish Government, Animal Health and Plant Health. Schools and researchers planning to import or export any biological materials will need to check the relevant information and obtain advice from the relevant regulator to determine whether any licence, authorisation or specific controls are required and comply with the applicable requirements. It is the responsibility of the School and individual importing or exporting the material to obtain these and any other required licences or authorisations. You should always contact the regulators if you uncertain about the need for any kind of license. Please apply for licenses well in advance of shipment as they take time to process and to ensure that all the relevant controls are in place.

8.1 Human Pathogens

There is no general requirement under health and safety law to obtain a licence to import biological agents into the UK other than the requirement to notify HSE of the movement of hazard group 4 biological agents which are in any case prohibited at the University of Edinburgh. There is no licensing system in the UK controlling the importation of human pathogens but there are requirements for HSE notification and consent under the COSHH Regulations and GMOCU Regulations which must be complied with before bringing certain biological agents or genetically modified organisms into the University. HSE must be notified in advance before any hazard group 3 biological agents and the hazard group 2 biological agents *Bordetella pertussis*, *Corynebacterium diphtheriae* and *Neisseria meningitidis* are brought into the university. There may be requirements to obtain a licence to export biological agents if listed in UK strategic export control lists and the pathogen is being exported to certain destinations.

8.2 Animal Pathogens

There is a requirement under various animal health laws to obtain a licence to import or export certain serious animal pathogens or related materials. The import of a specified animal pathogen into the UK requires a licence under the Importation of Animal Pathogens Order (IAPO) and a specified animal pathogen licence is needed under the Specified Animal Pathogens Order (SAPO) before premises can possess or use the specified pathogens including their carriers or any related materials. The licensing of imports of specified animal pathogens is regulated by Animal Health in Scotland. The licensing of research work with specified animal pathogens is regulated by HSE on behalf of Animal Health.

8.3 Plant Pathogens and Pests

There is a requirement under various plant health laws to obtain a licence to import or export certain serious plant pathogens and pests or related materials The import of a specified plant pathogen or pest into the UK requires a licence or authorisation under the Plant Health Order (PHO) and a separate plant health licence is needed before premises can possess or use the specified pathogens or pests including their carriers or any related materials. The licensing of imports of specified plant pathogens and pests is regulated by the Science and Advice for Scottish Agriculture (SASA) on behalf of Plant Health. The licensing of research work with specified plant pathogens and pests is regulated by SASA on behalf of Animal Health.

8.4 Genetically Modified Organisms

There is no specific licence required for importing or exporting genetically modified organisms other than the standard requirements for notification and consent and for licensing for specified animal pathogens or plant pathogens and pests. The HSE must

be informed as part of the notification process whether any class 3 genetically modified organisms are likely to be subject to any movement entering or leaving the UK or European Union (EU). The competent authorities may however require specific controls for the transport, import or export of certain genetically modified organisms.

8.5 Schedule 5 Pathogens and Toxins

There are no specific import licence requirements for many of the controlled pathogens and toxins listed in Schedule 5 under the anti-terrorism laws other than those required under other legislation. There are of course stringent controls on the possession or use of any pathogens or toxins which are subject to the terrorism laws. The School Biological Safety Adviser and University Biological Safety Adviser must be informed in advance of any intentions to acquire any pathogens or toxins listed on Schedule 5 and if any notification is required this will be made to Police Scotland by the Health and Safety Department. Please note that ricin and saxitoxin are listed on Schedule 1 of the Chemical Weapons Act and so require a specific licence from the CWC UK National Authority for their import, export, possession or use and it is necessary to comply with the other requirements of this legislation.

8.6 Biological Materials

There is a very broad range of biological materials which require licences to import export, possess or use them including various research and diagnostic materials, animals, plants, human tissues, animal materials, plant materials, soils, food products, agricultural products and environmental materials. There are so many types of licences which could be required that it is essential to check the relevant UK Government, Scottish Government, APHA, Animal Health and Plant Health regulatory websites for information and contact the regulators for specific advice where needed. The determination on whether or not a licence is required should be by the licensing authority and not the importer. Importers are advised to contact the regulator for advice on imports on a case by case basis if they are unsure whether a licence is required because even if one is not they may need written confirmation. In some cases where the material to be imported presents minimal risks a licence may not be required. However a letter to accompany the shipment should be obtained from the licensing office to confirm this is the case. The competent authorities such as the HSE, APHA, Animal Health or Plant Health may require specific controls for the transport, import or export of certain biological materials, animals or plants irrespective of whether or not they are covered by a licence.

9. Training for Transport of Biological Materials

The transport of dangerous goods, biological materials and infectious substances must be carried out by properly trained and competent workers. The specific requirements for the training of workers with responsibility for the transport of

dangerous goods and infectious substances are set out in the dangerous goods regulations and guidance. Personnel involved in the management of the transport of biological materials and infectious substances and provision of advice must receive appropriate certified training to ensure that they understand the relevant regulations and are competent to safely perform their duties. Personnel involved in the transport of biological materials and infectious substances must receive appropriate local training.

9.1 Local Training for Transport of Biological Materials and Infectious Substances

The safe transport of biological materials and infectious substances requires workers undertaking any role in the transport chain to complete appropriate local training so that they can carry out their responsibilities to the required standards. The level of training required varies but should be commensurate with the role and the associated responsibilities and must be recurrent to take account of changes in the regulations. In addition to local training, the Biosafety Unit delivers general training on the transport of dangerous goods, biological materials and infectious substances supplied in the transport of biological materials course.

9.2 Certified Training for Transport of Biological Materials and Infectious Substances

The safe transport of biological materials and infectious substances requires workers who are managing and providing advice on the transport of dangerous goods and infectious substances to complete an accredited training course. The Biosafety Unit organises a certified online training course through SafTPak on the safe transport of biological materials and infectious substances. The course is approved by IATA and the CAA and based on the international regulations developed by IATA and ICAO. This training course is primarily for the certification of School Biological Materials Transport Advisers but other additional workers may need to be trained. Schools must have trained advisers appointed to coordinate the packaging and transport of dangerous goods and infectious substances and ensure that this is carried out safely and in accordance with the regulations. School Biological Materials Transport Advisers must have completed an accredited training course and hold a current certificate. The training provides an understanding of the applicable regulatory requirements dealing with the identification, risk assessment, classification, packaging, marking, labelling and the required documentation for the transport of dangerous goods and infectious substances. The regulators require workers involved in the transport to be trained and certified every two years so certificates are valid for only two years and should be renewed as necessary. Certified training on the transport of dangerous goods and infectious substances should be recorded.

Document version

Version number	Summary of change	Date and by whom
V1.0	New template	JUNE 2023 HE
V1.1	Minor updates to text and links.	January 2024 PW

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