

# Transport of Infectious Substances

The GB regulations covering the carriage of dangerous goods by road and rail are derived from European Directives (ADR (road) and RID (rail)), which in turn implement international modal agreements governing the transport of dangerous goods. The GB regulations directly reference ADR in relation to the classification, packaging and labelling of all classes of dangerous goods, including infectious substances, and are updated every two years.

2 The requirements for air transport of dangerous goods, both within Great Britain and overseas, are contained in the International Civil Aviation Organisation (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air. They are essentially similar to those for road and rail as they mirror the same international modal agreements, but there are some minor differences (highlighted in the following text).

3 Biological agents, or materials that contain or may contain them, are allocated to UN Division 6.2 - infectious substances. Division 6.2 includes biological products, cultures, genetically modified micro-organisms (GMMs) and genetically modified organisms (GMOs) and medical/clinical waste.

## **Definitions (from ADR)**

### ***Infectious substances***

Infectious substances are substances that are known or are reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsia, parasites, fungi) and other agents such as prions which can cause disease in humans or animals.

### ***Biological products***

Biological products are those products derived from living organisms which are manufactured in accordance with the requirements of appropriate national authorities (in the UK: the Department of Health and the Medicines and Healthcare Regulatory Authority), which may have special licensing requirements, and are used either prevention, treatment or diagnosis of disease in humans or animals or for related development, experimental or investigational purposes. They include (but are not limited to) finished or unfinished products such as vaccines.

### ***Cultures***

Cultures (laboratory stocks) are the result of processes by which pathogens are amplified or propagated in order to generate in high concentrations, thereby increasing the risk of infection should exposure occur. This definition refers to cultures prepared for the intentional generation of pathogens and does not include cultures intended for diagnostic and clinical purposes.

### ***Genetically modified micro-organisms and organisms***

Genetically modified micro-organisms and organisms are those microorganisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

### ***Medical or clinical wastes***

Medical or clinical wastes are wastes that are derived from medical treatment of humans or animals or biological research.

### **Transport of infectious material**

There are 4 steps involved in the safe transport of infectious material. These are:

- Classification
- Packaging
- Labelling
- Transporting

### ***Classification***

Infectious substances are divided into the following categories:

**Category A:** an infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, lifethreatening or fatal disease to humans or animals. See Table A2 for indicative list. This includes all agents classified as HG4 in the Approved List of biological agents,<sup>24</sup> many HG3 agents and two HG2 agents (*Clostridium botulinum* and poliovirus). Those that can cause disease in humans or animals are assigned to UN 2814. Those that affect animals only are assigned to UN 2900 (additional requirements are in place for animal pathogens in the UK – see the DEFRA website<sup>72</sup> for further details). Exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.

**Category B:** any infectious substance that does not meet the criteria for inclusion in Category A. These are assigned to UN 3373, with the exception of cultures, which are assigned UN 2814 or 2900 as appropriate.

Samples of materials such as blood, tissue, excreta, secreta etc collected from humans or animals are considered, as a minimum, Category B infectious substances. For example, samples from otherwise healthy individuals or where there is no reason to suspect that they are suffering from a severe infectious disease. However, if there is evidence to suggest otherwise, eg on the basis of known medical history, local endemic conditions or professional judgement concerning the circumstances of the source material, then such material should be assigned to Category A.

GMMs or GMOs that do not meet the definition of an infectious substance but are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction are assigned to Class 9 (UN 3245).

Clinical or medical waste that contains Category B infectious substances (with the exception of cultures) or that only has a low probability of containing infectious substances is assigned to UN 3291.

The following substances are not subject to the provisions of the regulations:

- non-pathogenic micro-organisms (for either humans or animals)
- blood and blood components for transfusion or transplant and tissues or organs for use in transplants
- samples (non-human/animal derived) where there is only a low probability of infectious substances being present, eg food screening samples, environmental samples (water, soil etc) or else material (including material derived from human or animal sources) that has been treated to inactivate any infectious substances
- biological products that have been manufactured and packaged in accordance with MHRA/DH requirements, and are carried for the purposes of final packaging and distribution
- decontaminated clinical or medical waste
- live animals that have been intentionally infected or are known to be infectious (see Information box A2)
- GMMOs or GMOs when authorised for use by the competent authorities of the governments of the countries of origin, transit and destination

### ***Packaging***

Category A infectious substances (either UN 2814 or 2900) should be packed using Packaging Instruction 620 (PI620) (see Table A3). This packaging must meet UN performance requirements as shown by design type testing. These are known as UN-type approved packaging for Class 6.2 substances and they are certified and marked accordingly. Packaging for Category B infectious substances, packed using PI650, are not required to meet UN performance requirements provided they are capable of passing a 1.2 m drop test.

If air transport is to be used, the ICAO PI602 should be followed. The two instructions are essentially the same, but there are quantity limits imposed on material sent by air (see Information box A3).

Substances assigned to UN 3373 should be packaged in accordance with PI650 (see Table A3). The same PI number is used for air transport, but again there are limits on quantities that can be sent per package (see Information box A3).

If you send infectious substances packaged and labelled in accordance with PI650, no other requirements of the legislation apply.

### ***Labelling***

Packages containing infectious substances should be marked with:

- the proper shipping name, eg ‘Infectious substance, affecting humans’. (It is no longer necessary to show the technical name, ie the name of the microorganism, on the package but the proper shipping name should be supplemented with the technical name in the accompanying transport documentation)
- with the appropriate UN number (eg for ‘Infectious substances, affecting humans’ this would be UN 2814)
- the appropriate warning label. The danger sign for infectious substances is shown in Figure 4.

For frozen specimens being transported in an overpack, any certificated markings must be visible through the overpack or repeated on the overpack itself. The packaging should also be marked to indicate any subsidiary hazards.

### ***Transport***

Although the regulatory requirements only apply to transport of infectious material off site, on-site transport still needs to be carried out in a safe manner. Further detail on this can be found in *Safe working and the prevention of infection in clinical laboratories and similar facilities*.<sup>14</sup>

Transport between one part of private premises and another part of those premises situated in the immediate vicinity of that first part, where both parts are occupied by the same person even if those parts may be separated by a road, does not fall within the scope of the regulations.

You should always discuss your transport requirements with your chosen carrier, in particular, you may need to provide some of the information that will be used on the accompanying documentation. You will need to establish whether any of the intended transport will be by air, even within the UK, to ensure that the correct packaging is used and that quantity limits are not exceeded. The detail of the documentation that may be required is not given here. You should consult your carrier about this information, as it may vary depending on the carrier and/or the final destination.

In general, samples that are sent using UN 3373 can normally be sent via the postal service. Packaging will need to comply with the ICAO standards, as a proportion of the post in the UK will travel by air at some point in its journey.

## **PACKAGING INSTRUCTION PI650**

This packing instruction applies to UN 3373

The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during carriage, including trans-shipment between vehicles and containers and between vehicles or containers and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling.

Packagings shall be constructed and closed to prevent any loss of contents that might be caused under normal conditions of carriage by vibration or by changes in temperature, humidity or pressure.

The packaging shall consist of three components:

- (a) a primary receptacle
- (b) a secondary packaging
- (c) an outer packaging.

Primary receptacles shall be packed in secondary packagings in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packagings shall be secured in outer packagings with suitable cushioning material. Any leakage of the contents shall not compromise the integrity of the cushioning material or of the outer packaging.

For transport, the mark illustrated in Figure 5 shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The width of the line shall be at least 2 mm; the letters and numbers shall be at least 6 mm high.

The completed package shall be capable of successfully passing the drop test set out in the regulations except that the height of the drop test shall not be less than 1.2 m. The smallest external dimension of the outer packagings shall not be less than 100 mm.

For liquid substances:

- (a) The primary receptacle(s) shall be leakproof.
- (b) The secondary packaging shall be leakproof.

(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.

(d) Absorbent material shall be placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substances will not compromise the integrity of the cushioning material or of the outer packaging.

(e) The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar).

For solid substances:

(a) The primary receptacle(s) shall be siftproof.

(b) The secondary packaging shall be siftproof.

(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.

Refrigerated or frozen specimens: Ice, dry ice and liquid nitrogen:

(a) When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these regulations shall be met. When used, ice or dry ice shall be placed outside the secondary packagings or in the outside packaging or an overpack. Interior supports shall be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack shall be leakproof. If carbon dioxide, solid (dry ice) is used, the packaging shall be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up pressure that could rupture the packagings and shall be marked "Carbon dioxide, solid" or "Dry ice".

(b) The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures that could result if refrigeration were lost.

Infectious substances assigned to UN 3373 and are packed and marked in accordance with this packing instruction are not subject to any other requirement in these Regulations.

Clear instructions on filling and closing such packages shall be provided by packaging manufacturers and subsequent distributors to the consignor or to the person who prepares the package (eg patient) to enable the package to be correctly prepared for transport.

If any substances has leaked or has been spilt in a vehicle or container, it may not be reused until after it has been thoroughly cleaned, and, if necessary disinfected or decontaminated. Any other goods or articles carried in the same vehicle or container shall be examined for possible contamination.

## **UN 3373**

This is taken from the HSE Website ([www.hse.gov.uk](http://www.hse.gov.uk)). For further information and more details, please refer to their website under Biological Agents: Managing the risks in laboratories and healthcare premises.