University Occupational Health and Safety Guidance Notes

THE TRANSPORT OF GENETICALLY MODIFIED MICRO-ORGMANISMS / ORGANISMS

1. Purpose

This Guidance Note should be used in conjunction with the Guidance Note on Transport of Infectious Substance.

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 is the main UK legislation that covers transport by road and rail. The approach to safe transport of infectious substances is similar for the different modes of transport but, in general, substances sent via air require more stringent packaging. The Technical Instructions for the Safe Transport of Dangerous Goods by Air published by the International Civil Aviation Organization (ICAO) are the legally binding international regulations. The ICAO rules apply on all international flights. For national flights, i.e. flights within one country, national civil aviation authorities apply national legislation. This is normally based on the ICAO provisions, but may incorporate variations. The International Air Transport Association (IATA) publishes Dangerous Goods Regulations (DGR) that incorporates the ICAO provisions and may add further restrictions. State and operator variations are published in the ICAO Technical Instructions and in the IATA Dangerous Goods Regulations. There are 3 steps involved in the safe transport of infectious material: Classification; Packaging and Labelling; and Transport.

2. IATA training

When transporting Infectious Substances by air, it is a legal requirement that personnel who package and arrange for air transport by courier must be trained under the condition set out in The Technical Instructions for the Safe Transport of Dangerous Goods by Air, further information can be obtained from SHaW. The training needs of each individual should be identified according to a Departmental training matrix. The checklist forming part of the Occupational Health and Safety Induction - Part 2 can be utilised to establish initial training and specific training can be identified and fulfilled as required.

3. Classification and Labelling

For classification purposes, the GMM should first be assessed to see if it is capable of causing disease in humans or animals i.e. would work with the GMM in the laboratory mean that it is classified as being in Activity Class 2 or higher. If so, then it should be classified for packaging purposes as Category A or B as appropriate. Movement of Class 3 GMMs is also subject to prior notification to the Health and Safety Executive.

If the GMM is not infectious for humans but is still able to alter animals, plants or other micro-organisms in a way that does not occur naturally, e.g. GMMs that could be classified as Activity Group 1 but which are vectors and can transfer genetic material to other organisms, are classified as Class 9 (Miscellaneous dangerous goods). They are assigned to UN 3245 and their proper shipping name is GENETICALLY MODIFIED MICRO-ORGANISMS.

GMMs which are not infectious and not able to alter animals, plants or other micro-organisms are **not** considered hazardous for transport but they should be packaged in such a way so they do not leak during transport.

Naked DNA or proteins derived from GMMs
Such material e.g. plasmids, as well as non-modified proteins and other biological material generally, e.g. antibodies, are not considered hazardous for transport but such material should be packaged in

such a way so they do not leak during transport. Depending on the source of the material, it may be subject to import/export control (usually material of animal origin).

4. Packaging

General principles of packaging

All potentially infectious substances must be packed using a triple layer system:

a. **Primary receptacle** – a primary watertight, leak-proof (or sift-proof for solids) containing the infectious substance, packaged with enough absorbent material to absorb all fluid in case of breakage;

b. **Secondary packaging** – a second durable, watertight, leak/sift-proof packaging to enclose and protect the primary receptacle(s). 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

c. **Outer packaging** – secondary packaging is placed in an outer shipping packaging with suitable cushioning material. Outer packaging should protect contents from physical damage during transit.

Each category of infectious substance should be packaged and labelled in accordance with the relevant Packing Instruction along with relevant documentation.

5. Transport

5.1 Campus Transport

A container specifically designed for transporting biological substances should be used for the transport of biological material, including GM material on campus. The BioTranport Carrier below is an example of such a container (Fisher Scientific). A spill kit should be carried along with the biological material.

5.2 Off campus transport

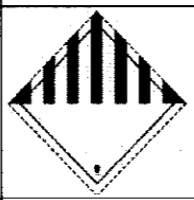
Classification, packaging, labelling and documentation summary tables

The following tables are taken from the Carriage of Dangerous Goods Regulations (The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 ("CDG 2009"), SI 2009 No 1348, which came into force on 1 July 2009. The tables summarise the packaging, labelling and documentation requirements for Category A and Category B infectious substances, exempt human or animal specimens and GMMs able of altering animals, plants or other micro-organisms in a way that does not occur naturally. Differences between different modes of transport are highlighted. Emergency responses can be found in Appendix 6 of the Regulations

Summary Table 4 - GMMs assigned to UN 3245

UN number/proper shipping name:	UN 3245 – GENETICALLY MODIFIED MICROORGANISMS or GENETICALLY MODIFIED ORGANISMS (NB: classified as Class 9: Miscellaneous)	
Packing instruction	Air: PI 913	Must be packed in accordance with PI 602/620 but packagings do not need to be tested
	Road/Rail: PI 904	
Quantity limits	Air: Primary receptacle should not exceed 100ml/100g but no total limit specified	
	Road: no limits	
Testing of packaging	Does not require testing (see above)	
Minimum dimension of outer packaging	At least one surface of outer packaging should be minimum of 100mm x 100mm	
Hazard label	 Minimum dimensions of 100mm x 100mm (for small packages 50 x 50). Black text/lines on a white background.	
Other information to be displayed on outer packaging	The words "GENETICALLY MODIFIED MICROORGANISMS or GENETICALLY MODIFIED ORGANISMS" should be clearly visible and displayed on the outer packaging. Consigner/consignee name and address, name and number of emergency contact (24hrs) should also be displayed.	
Documentation	Copies of paperwork must be included within the package and also be provided to accompany the package (for the carrier). Paperwork (ideally on University headed paper) must be included within the package between the secondary and the outer (attached to the secondary), giving the names and addresses of consignor/ consignee including emergency contact details (name and telephone number) at both ends, together with a description of the goods as follows: UN 3245: GENETICALLY MODIFIED MICROORGANISMS or GENETICALLY MODIFIED ORGANISMS. In cases where the package will be going through customs, a statement should be added, where appropriate, that they are research materials of no commercial value. Written emergency response procedures (See Appendix 6) For transport by air it is necessary to complete an Air Waybill and a Shipper's declaration is required.	

Summary Table 5 - Dry ice

UN number/proper shipping name:	UN 1845 – DRY ICE or CARBON DIOXIDE, SOLID
Packing instruction	Air: PI 904
	Road/Rail: Not subject to dangerous goods regulations
Quantity limits	Air: No more than 200kg per package. Where non hazardous biological material is carried in hand luggage or in checked-in luggage, no more than 2.5kg is allowed.
	Road: no limits
Testing of packaging	Does not require testing but packaging used must allow build of CO_2 to escape
Minimum dimension of outer packaging	N/A
Hazard label	 Minimum dimensions of 100mm x 100mm (for small packages 50 x 50). Black text/lines on a white background.
Other information to be displayed on outer packaging	The words "DRY ICE or CARBON DIOXIDE, SOLID" and the net weight of dry ice in the package should be displayed
Documentation	When using dry ice to transport infectious substances and other biological material, relevant paperwork must be included within the package and also be provided to accompany the package (for the carrier). Paperwork (ideally on University headed paper) must be included within the package between the secondary and the outer (attached to the secondary), giving the names and addresses of consignor/ consignee including emergency contact details (name and telephone number) at both ends, together with a description of the goods as well as information about the dry ice as follows: UN 1845: "DRY ICE or CARBON DIOXIDE, SOLID". In cases where the package will be going through customs, a statement should be added, where appropriate, that they are research materials of no commercial value. Written emergency response procedures (See Appendix 6) if the package contains material classified as UN 2814, 2900, 3373 or 3245. For transport by air it is necessary to complete an Air Waybill. A Shipper's declaration will be required if the dry ice is being used to transport substances classified UN 2814 , 2900, 3373 or 3245 by air – but even when not required it may be requested by certain couriers/airlines.

6. Importing and exporting GMMs

Under the Cartagena Protocol on Biosafety (the first Protocol to the Convention on Biodiversity) GMMs destined for Contained Use are excluded from the majority of the requirements of the protocol, e.g. advanced informed agreement arrangements, as this is meant primarily for organisms destined for deliberate release. However, when exporting GMOs/GMMs for contained use, it is necessary to:

- Ensure the GMOs/GMMs are transported safely - the GMOs/GMMs must be classified, packaged and labelled in accordance with the relevant transport regulations;
- Provide certain information in accompanying documentation - some of the information required for example, contact details for further information and the name and address of the person to whom the consignment is being sent, is already included in paperwork necessary to comply with the transport regulations; and
- Provide additional information as follows - a statement that the package contains or consists or GMMs giving a basic description of the host and how it has been modified, any unique identification code(s) assigned to the GMMs if such codes exist and any requirements for safe handling, storage, transport and use. This can be achieved by enclosing a copy of relevant parts of the GM risk assessment. However, you should note you must make an explicit statement that the package contains GMMs and not just assume it is implicit by providing a copy of the GM risk assessment.

The HSE must be informed (as part of the notification process for Class 3 activities) whether Class 3 GMMs are likely to be subject to any movement entering or leaving the EC. HSE then informs the Biological Clearing House and European Commission of such movements.