EUROPEAN BIOLOGICAL RESOURCE CENTRES
NETWORK INFORMATION RESOURCE

International Regulations for Packaging and Shipping of Microorganisms

This revised EBRCN information resource is based on the UN Model Regulations for the Transport of Dangerous Goods, 16th edition, United Nations. A basic information document is also the WHO publication "Guidance on regulations for the Transport of Infectious Substances 2007-2008, WHO/CDS/EPR/2007.2

Key words: UN Model Regulations, UN numbers, ICAO, IATA, UPU, dangerous goods, infectious substances, postal mail/freight, couriers, "known shipper", aviation security, trained person. Biological materials, shippers declaration, packaging, microorganism, genetically modified organism

Abbreviations used in the text

ADR	The European regulation on the transport of dangerous goods on the road
DGR	IATA Dangerous Goods Regulations, the guide recognised by the world's airlines
PI	Packing Instruction
PSN	Proper Shipping Name of a given dangerous good
UN number	it is the unique number referring to a dangerous good
dg	dangerous good

Introduction

Before a consignment containing microorganisms is offered for transport, the decision whether or not it includes an infectious substance is as crucial as its destination. In order to select the correct packaging and mode of transport/carrier (postal mail or courier), shippers of biological material must have a sound knowledge of all relevant packaging and transport regulations. They must have recurrent training according to the latest *IATA* Dangerous Goods Regulations (DGR, chapter 1.5) if infectious substances are transported by air. Air transport plays the dominant role in setting requirements when living biological materials are transported over long distances. Furthermore, the DGR for air transport make sure the responsible shipper is on the safe side and in conformity with international law. Also, national or regional regulations for road transport must be observed (e.g. ADR in Europe).

Infectious substances are dangerous goods Class 6, Division 6.2, and all regulations for transport of dangerous goods fully apply so that they don't present a hazard to people involved in the transportation chain, to animals or the environment. This does not usually apply to microorganisms classified in Risk Group 1. For the latter, other regulations for packaging and transport have to be observed. They can usually be transported by postal mail services when packed in accordance with the respective packaging regulations laid down by the Universal Postal Union (UPU). Postal services differentiate between perishable (active) and non-perishable (dried, freeze-dried) biological substances. Shippers should be aware that any biological material is excluded from transport in postal parcels, UPU permits letter mail only (UPU Letter Post Manual Articles 16 and RL 129). The term "freight" is used in connection with courier transport, in contrast to postal parcels. Registered letter mail is recommended because of individual treatment and the potential for tracking. Also note that in general, postal mail systems exclude any dangerous goods. However, infectious substances classified in shipping Category B *might* be sent by national postal mail (by road). There are strict requirements on shipper's responsibility and packaging quality, on correct labelling and marking. For shippers of UN 3373 (see below) face-to-face training courses are not obligatory in all countries, it depends on the decision by the national aviation authority, but having knowledge is obligatory for all shippers.

The Risk Group allocation of an organism helps the sender classify the material for transport purposes. Principally, the requirements of Category B apply to the majority of Risk Group 2 microorganisms:

such cultures can be shipped under the same requirements as diagnostic specimens, using the same UN number 3373 and Packing Instruction PI 650 packaging. Neither a Shipper's Declaration for dangerous goods form (a similar form for road transport) nor a transport emergency card is required. The strong UN packaging meeting PI 620 requirements are of course permitted for UN 3373 and can be recommended as they better withstand air vibrations, changes in temperature or high pressure during air transport. They have passed stricter tests compared to PI 650 packaging and, due to a growing market, packaging prices have dropped dramatically.

The transportation chain begins in the packaging department of an institute, ends in the recipients' laboratory and may include transport by hand, postal or courier transport, this may be within countries or across borders and continents. Only a correctly labelled and documented shipment reaches its destination quickly and safely, therefore the courier services require their customers (shipper) to fulfil the regulations. It is the responsibility of all laboratories supplying infectious substances to nominate a person who receives recurrent training and takes the responsibility for signing shipping documents (in case of Category A shipments). The latter can ONLY be signed by a trained person (*IATA* DGR chapter 1.5, Training Requirements) who is thoroughly conversant with the regulations including the applicability, limitations (state or operator variations), classification, identification, packing, marking, labelling and documentation. If infectious substances meeting the definition of Category A, UN 2814 or UN 2900 respectively, are shipped, an experienced approved courier shall be chosen, advance arrangements with courier and consignee are absolutely necessary. Transport of UN 2814/UN 2900 on the road underlies restrictive dg mass limitations per transport vehicle so that sometimes individual transports are required to carry a single packaging (specialised couriers).

Furthermore, Category A meets the definition of "high consequence dangerous goods" and requires a security plan (DGR 1.6.3) in order to secure the packaging during transport and to prevent loss, theft, damage etc. For reasons of air security, in Europe the EU Council regulation 300/2008 came into force in April 2010 (national laws on air security) affecting all shippers who are registered "Known Shippers". They have to be approved by the resp. national aviation authority to receive this status. It means that such shippers have to implement an internal air security plan involving the complete internal chain of risk management and process management until a packaging is delivered. Known shippers are privileged insofar as the forwarding process is accelerated and packaging are usually not X-rayed.

The most important definitions acc. to IATA DGR 52th ed 2011

3.6.2.2.1 Infectious substances must be classified in Division 6.2 and assigned to UN 2814, UN 2900 or UN 3373, as appropriate.
3.6.2.2.2 Infectious substances are divided into the following categories:
3.6.2.2.2.1 Category A: An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. Indicative examples of substances that meet these criteria are given in Table 3.6.D (DGR 52nd ed.). Note: this Table is not exhaustive. It contains microorganisms that more or less meet the definitions of the Risk Groups 3 and 4.
3.6.2.2.2.2 Category B: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B must be assigned to UN 3373.
Note: The Proper Shipping Name (PSN) of UN 3373 is "Biological substance, Category B".
3.6.2.4 Genetically Modified Microorganisms and Organisms
3.6.2.2.4.1 Genetically Modified Microorganisms not meeting the definition of an infectious substance must be classified according to Subsection 3.9.
3.9.1.2 Genetically Modified Microorganisms (GMMOs) and Genetically Modified Organisms (GMOs) are organisms (microorganisms) in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

3.9.2.5.1 GMMOs and GMOs which do not meet the definition of infectious substances but which are capable of altering animals, plants or microbiological substances in a way which is not normally the result of natural reproduction. They must be assigned to UN 3245.

The Proper Shipping Name

The majority of the Risk Group 2 organisms can be sent under UN 3373 with the unique PSN "Biological substance, Category B". The former shipping names "Diagnostic specimens"/"Clinical specimens" are not permitted anymore! The PSN has to be printed in letters at least 6 mm high and must be marked on the outer package adjacent to the diamond-shaped label UN 3373.

Packing Instructions PI 650 and PI 620

All responsible shippers of biological material must be conversant with these PIs. IATA PI 650 describes a UN-certified packaging system with less strength and usually smaller dimensions than IATA PI 620. See recommendations in this text. PI 620 must be used for Category A. They can also be used for Cat. B infectious substances, but there is no legal need to use this strong packaging for Cat. B.

Before dispatch of cultures: Export control

The sender of a microorganism must be sure that the receiver is authorised to work with it and has adequate facilities:

1. No supply to private persons
2. No supply to new/unknown recipients who have not specified their institution
3. Only supply infectious substances to recipients who have the appropriate laboratory safety level (containment) corresponding to the Risk Group of the organism
4. Only supply animal or plant pathogens or genetically modified organisms to recipients having an appropriate laboratory and the relevant permits for work

When shipping outside the country, the sender must be sure that the microorganism does not fall under export restrictions. The Australia Group list including its Warning List shall be observed as well as national regulations on export restrictions on dual-use goods. Relevant national Authorities are the national Export Offices, Departments of Commerce or Foreign Offices. If applicable, quarantine requirements must be fulfilled by the receiver and import permits (from Health Authorities) must be shipped together with the organism.

It is recommended for all institutions shipping biological materials, especially infectious substances, to

1) establish a well-organised shipping department with trained staff
2) nominate a trained person who replaces the trained shipper in cases of absence
3) have access to the latest *IATA* Dangerous Goods Regulations, to the latest regulations for road transport of dangerous goods and to all further relevant information sources
4) develop a step-by-step checklist (see below)
5) establish a computerised system for filling in the shipping documents in order to have a fast and reliable system that avoids mistakes and to document any dispatch

Step-by-step checklist for shippers

The following short checklist may help in the proper packing and shipping of biological materials.

International shipments

1. *Is a permit or export license needed to distribute the ordered material?*
   >>>Only written orders should be accepted and in case of regulated/listed organisms an end user certificate is recommended if not required by law. If unclear, contact your national authority.
2. *Are there any import or quarantine restrictions for the customer's country?*
   >>>Some countries require an import permit for certain microorganisms (the recipient should provide the permit, it should accompany the consignment).

3. *Does the order include any infectious substances (Risk Group 2 - 4 organisms)?*
   >>>If YES, these are dangerous goods and therefore all packaging and shipping requirements must be adhered to e.g. ADR (road) in Europe or IATA (air) internationally. Continue with 4 and 5. If NO, see under 6.
4. *Is the recipient qualified and authorized to handle the ordered cultures?*
   >>>Recipients of cultures must confirm by written statement that they are entitled to receive and handle infectious biological materials, especially those of Risk Group 3 and 4 organisms (it may be also a requirement for Risk Group 2 organisms). Is an export license required (national legislation may restrict distribution of some organisms, their derivatives or nucleic acids)?
5. *Do the National Postal Authorities concerned (sender's, transit and customer's countries) accept infectious substances in the mail (observe IATA DGR 2.4 and UPU restrictions)?*
   >>>If YES, the order can be sent by mail (rarely permitted!). If NO, the order may be sent by (air) freight only. Category A infectious substances (UN 2814 or UN 2900, resp.) are excluded from any postal mail. Category B infectious substances (UN 3373) may be sent by national postal systems on the road (observe packaging sizes PI 650 and PI 620).
6. *Are non-infectious perishable cultures (agar/liquid "active cultures") to be included in the package?*
   >>>If YES, continue with 7. If NO, see under 8.
7. *Do the National Postal Authorities concerned accept non-infectious perishable biological substances in the mail?*
   >>>If YES, the order can be sent by registered airmail letter according to the relevant **UPU** packing requirements (see Example cases below). If NO, the order might be sent by (air) freight only.
8. *Does the shipment contain only non-infectious and non-perishable (dried or freeze dried) biological substances?*
   >>>If YES, the shipment can be sent by mail according to the relevant **UPU** packing requirements, preferably registered mail (see Example cases below).

National shipments

1. *Does the order include any infectious substances (Risk Group 2 - 4 organisms)?*
   >>>If YES, these are dangerous goods and therefore all packaging and shipping requirements must be adhered to e.g. ADR in Europe (road) or specific national requirements.
2. *Is the recipient qualified to handle the ordered cultures?*
   >>>Recipients must confirm by written statement that they are entitled to receive and handle infectious biological materials and/or they are obliged to send a copy of the resp. working permit.
3. *Does the National Postal Authority accept infectious substances in the mail (observe IATA DGR 2.4 if applicable and UPU restrictions)?*
   >>>If YES (rarely permitted!), the order can be sent by mail if the required packaging is in conformity with the resp. national postal requirements. If NO, the order may be sent by courier only.
4. *Are non-infectious perishable cultures (agar/liquid "active cultures") to be included in the package?*
   >>>If YES, continue with 5. If NO, see under 6.
5. *Does the National Postal Authority accept non-infectious perishable biological substances in the mail?*
   >>>If YES, the order can be sent by registered letter mail according to the relevant **UPU** packing requirements (see Example cases below). If NO, the order might be sent by courier only.
6. *Does the shipment contain only non- infectious and non-perishable (dried or freeze dried) biological substances?*
   >>>If YES, the shipment can be sent by (non-registered) mail according to the relevant **UPU** packing requirements (see Example cases below).

Example cases

Case A

The organism to be sent is non-infectious, not genetically modified (does not fall under UN 3245, see Case D) and its distribution is not restricted under law >> It may be sent nationally or internationally by postal letter mail, dependent on the regulations of the Postal Administrations of sender's, transit and receiver's countries. >> If permitted by Postal Administrations, the microorganism can be shipped by (registered) air mail letter according to UPU Articles 16 and RL129 requirements. The minimum strength of a triple packaging must be used. Principally, there is no accepted packaging with less strength than PI 650. >> If not permitted by Postal Administrations, freight (courier) must be used.

Case B

The organism to be sent is infectious but if exposure to it occurs it is not capable of causing permanent disability, life-threatening or fatal disease to humans or animals and does not meet the definition of Category A. It meets the definition of Category B, UN 3373 (the majority of Risk Group 2). >> Such organisms including laboratory cultures are dangerous goods of Class 6, Division 6.2 and can be sent according to PI 650, DGR. A Shipper's Declaration for Dangerous Goods is **not** required. The Proper Shipping Name is "Biological Substance, Category B". Shipment by airmail is usually prohibited; some national postal services may permit intra-national transport on the road.

Case C

The organism to be sent is an infectious substance, affecting humans (UN 2814) classified in Risk Group 3 or 4 and/or the definition of Category A applies or it is affecting animals (UN 2900) meeting the Category A definition >> Such an organism must be shipped as a Class 6.2 dangerous good by freight, any postal mail is prohibited (DGR 2.4). When shipping infectious substances of Category A, independently of the net weight, the UN Model Regulations apply for **all** modes of transport requiring a UN certified combination packaging system acc. to PI 620. The shipper is a trained person and is responsible for the consignment including all documents (IATA DGR 1.5) including the Shipper's Declaration for Dangerous Goods form.

Choose experienced courier services and clarify ALL steps **before** offering the consignment to the courier (destination manageable? Door-to-door or door-to-airport delivery?). Make advance arrangements with the consignee (DGR 8.1.6.11.4). Observe the DGR Limitations chapter. Transport of these cultures is usually individual.

Case D

The organism to be sent is genetically modified (GMO). The DGR and other transport regulations distinguish 2 kinds of GMOs: an infectious substance that is genetically modified must be shipped as >> UN 2814/UN 2900 (Category A) or UN 3373 (Category B) respectively (for the latter see Case B). Animals containing or being contaminated with GMOs or infectious substances, must not be transported by air unless exempted under IATA DGR 2.6.1. GMOs that are not infectious substances but capable of altering animals, plants or microorganisms in a way which is not normally the result of natural reproduction must be classified in >> Class 9 (Miscellaneous Dangerous Goods) and assigned to UN 3245. >> Note: PI 959 applies; the Class 9 label is required (black and white stripes). A Shipper's Declaration for dangerous goods form is required!

Case E

Carbon dioxide, solid, dry ice, is used for shipping an organism. >> Dry ice is a dangerous good (Class 9, UN 1845) and must be packed acc. to PI 954. Packaging systems for shipping UN 2814/UN 2900 or UN 3373 infectious substances together with dry ice are commercially available. Such packaging systems fulfil both packing requirements, for infectious substances and for dry ice and carry both, dangerous goods labels and specification markings. If dry ice is added in a packaging that contains dg requiring a Shipper's Declaration for dangerous goods form, the dry ice must be mentioned on this form. Dry ice itself does not require a Shipper's Declaration for dangerous goods form. Dry ice must always be mentioned on the air waybill.

Some general hints for safe packaging

- Petri dishes as primary receptacles should be avoided if possible.
- Screw caps, glass material and seals used for primary receptacles should be of good quality so that leakage is avoided during transport.
- For infectious substances, only industrially available certified UN packaging systems are permitted, no other self-made combinations.
- When packaging is re-used, it must not have any signs of damage or previous leakage.

Associated example materials as appropriate

- Labels as required (if not directly printed on outer packaging surface)
- Air transport: Shipper's Declaration for Dangerous Goods (for UN 2814/UN 2900/UN 3245)
- Air transport: Air waybill (waybill: for all modes of transport by courier)
- Documents such as quarantine import permits and working permits if applicable
- Information on handling & safety ("Material Safety Data Sheet") and contact persons' name and telephone number
- List of contents in the consignment and information on categorisation of hazard group

International Organisations

IATA: the International Air Transport Association annually updates the Dangerous Goods Regulations (DGR), the legally binding basis for shippers and carriers of dangerous goods for air transport.

ICAO: the International Civil Aviation Organization Council uses the UN Model Regulations as the basis for the Technical Instructions for the Safe Transport of Dangerous Goods by Air (updated every two years).

UN: the United Nations Committee of Experts on the Transport of Dangerous Goods publish the Recommendations on the Transport of Dangerous Goods ("Orange Book"), being the basis = "Model Regulations" for international transport regulations for dangerous goods for all carriers (air, road, rail, waterways).

UPU: the Universal Postal Union publishes the International Postal Convention through the Letter Post Compendium (constantly updated).

WHO: the World Health Organization defines the Risk Groups for classification of biological substances and published the "Laboratory Biosafety Manual (WHO/CDS/CSR/LYO/2004.11)", the "Guidance on Regulations for the Transport of Infectious Substances" (WHO/CDS/EPR/2007.2) and the "Biorisk Management Laboratory Biosecurity Guidance" (WHO/CDS/EPR/2006.6).

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