EUROPEAN BIOLOGICAL RESOURCE CENTRES
NETWORK INFORMATION RESOURCE

# International Regulations for Packaging and Shipping of Microorganisms

***This EBRCN information resource has been revised according to the 2005 changes***

- ***in the UN Model Regulations on the Transport of Dangerous Goods 13th edition (ST/SG/AC.10/1/Rev.13), adopted by the UN SCETDG Committee***
- ***in Addendum Doc 9284-AN/905 to the ICAO Technical Instructions 2005-2006 Edition,***
- ***in Addendum II of March 2005 to the 46th Edition of the IATA Dangerous Goods Regulations***

## INTRODUCTION

Before a consignment containing microorganisms is offered for transport, the decision whether or not it is an infectious substance is crucial as is the destination of the consignment. In order to select the correct type of packaging and the correct 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 dominating role when living biological materials are transported over long distances. Furthermore, the Dangerous Goods Regulations for air transport are most user-friendly making sure the responsible shipper is on the safe side and in conformity with international law. It is self-evident that the respective national or regional regulations for road transport have to be observed (e.g. ADR in Europe).

Infectious substances are by definition dangerous goods (Class 6, Division 6.2) and the Dangerous Goods Regulations for transport fully apply so that they don't present a hazard to people involved in the transportation chain, to animals or the environment. This does usually not apply to microorganisms classified in Risk Group 1. For the latter, consequently other regulations for packaging and transport are in place and 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 usually 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. The term "freight" is used in connection with courier transport only, in contrast to postal parcels. Registered letter mail is generally recommended because of individual treatment and possible tracking. Also note that in general, postal mail systems exclude any dangerous goods, infectious substances classified in the new shipping Category B *might* be sent by national postal mail (on the road). The new deregulated transport requirements for Category B cultures imply that administrational expenditure and costs have become much less problematic. However, there are still strict requirements on shipper's responsibility, training and packaging quality as well as on correct labelling and marking.

Although the recent changes relevant for shippers of infectious substances resulted in the definition of a new classification system using two new shipping Categories A and B instead

of using the Risk Group definitions, the existing Risk Group allocation of an organism does help the sender to classify the material for transport purposes. Additionally, the regulations for shipping genetically modified organisms (GMO) have undergone a revision resulting in a clearer instruction for transport of safety level 1 GMO (class 9, miscellaneous dangerous goods, see below). Principally, the new deregulated requirements apply to the majority of Risk Group 2 microorganisms as the definition of this Risk Group conforms with the definition of the new Category B (see below): such cultures can be shipped under the same requirements as diagnostic specimens, using the new UN number UN 3373 and Packing Instruction PI 650 packaging. A Shipper's Declaration for dangerous goods form is not required anymore, neither a similar form for road transport nor a transport emergency card. However, with regard to strength and quality, UN packaging meeting the PI 602 requirements are strongly recommended as they withstand air vibrations, changes in temperature or high pressure during air transport. They have passed different tests compared to PI 650 packaging and because of a growing market prices have dropped drastically.

The transportation chain begins in the packaging department of a Culture Collection, ends in the recipients' laboratory and may include transport by hand, postal or courier transport, this maybe 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 to fulfil the regulations. It is the responsibility of all laboratories supplying infectious substances to nominate a person who receives recurrent training and who takes the responsibility for signing the 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 and labelling and documentation. If substances meeting the definition of the new shipping Category A, UN 2814 or UN 2900 respectively, an experienced courier should be chosen, advance arrangements with the courier and with the consignee are necessary. Transport is mostly performed as individual transport due to new more restrictive total dangerous goods mass limitations in transport vehicles.

## THE MOST IMPORTANT DEFINITIONS acc. to IATA DGR 46th Ed. 2005 and Addendum II to these DGR

**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 to humans or animals. Indicative examples of substances that meet these criteria are given in Table 3.6.D (p. 96, IATA DGR 46th 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 "Diagnostic specimens", "Clinical specimens" or "Biological substance, Category B".

*The exemption of the cultures under this paragraph has been withdrawn by IATA DGR Addendum II*.

**3.6.2.4 Genetically Modified Microorganisms and Organisms**

**3.2.6.2.4.1 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 microorganisms and organisms 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.

**A NEW UN NUMBER, A NEW PROPER SHIPPING NAME (PSN)**

The recent major breakthrough is that the majority of the Risk Group 2 organisms can now be sent under UN 3373 with the new PSN referring to a microbiological culture ("Biological substance, Category B"). This affects most Culture Collections. Addendum II to the DGR 46th Ed. admits, "On 1 January 2007, it is anticipated that the use of the shipping names Diagnostic specimens and Clinical specimens will no longer be permitted". 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.

**CATEGORY A AND CATEGORY B**

The introduction of the two new Categories for transport purposes replacing the Risk Group definitions for shipping is a more realistic approach, it makes deregulated transport of a very large number of low-risk bearing cultures possible.

**PACKING INSTRUCTIONS PI 650 and PI 602**

All responsible shippers are asked to be conversant with both of these Packing Instructions. IATA PI 650 describes a UN-certified packaging system with less strength and smaller dimensions than IATA PI 602 (= UN/ICAO PI 620). See recommendations in this text. Preferably, UN packaging fulfilling the PI 602 requirements should be used also for Cat. B infectious substances.

**THE PREMISES BEFORE DESPATCH OF CULTURES**

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

1. Do NOT supply to private persons
2. Do NOT supply to new customers/unknown recipients who have not specified their institution
3. Only supply of infectious substances to recipients who have the appropriate laboratory safety level which corresponds with the Risk Group of the organism

4. Only supply of 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 also be sure that the microorganism does not fall under export restrictions like the Biological and Toxin Weapons Convention, Dual-use restrictions and other national legislation (relevant national Authorities are the national Export Office, Department of Commerce or the Foreign Office) and that, if applicable, quarantine requirements are fulfilled by the receiver and import permits (from Health Authorities) are ready to be shipped together with the organism. Please, also see the resp. EBRCN Information Resource documents for further information.

**It is important for Culture Collections to**

1) establish a well-organised shipping department with trained staff
2) nominate a trained person who replaces the legal 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 like below
5) establish a computerised system for filling in the shipping documents in order to have a fast and reliable system that avoids mistakes

**STEP-BY-STEP CHECKLIST FOR SHIPPERS**
The following short instructions may be helpful in the proper packing and shipping of biological materials.

**<u>International shipments</u>**

**1. Is a permit or export license needed to distribute the ordered material outside the sender's country?**
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 (the Department of Commerce, Export Office or Foreign Office).

**2. Are there any import or quarantine restrictions of the customer's country?**
Some countries require an import permit for certain microorganisms (the recipient should provide this permit that accompanies 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 a written statement that they are entitled to receive and handle infectious biological materials, especially those of Risk Group 3 and 4 organisms (in some countries this is also a requirement for Risk Group 2 organisms). Is an export license required for the recipient culture (national biosecurity may restrict distribution of some organisms, their derivatives or products.

**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 might be sent by (air) freight only. Category A infectious substances (UN 2814 or UN 2900, resp.) are excluded from any postal mail transport. Category B infectious substances (UN 3373) maybe sent by national postal systems on the road (see packaging sizes PI 650 and PI 602).

6. **Are *non-infectious perishable* cultures (agar or 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). 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 (non-registered) airmail according to the relevant **UPU** packing requirements (see EXAMPLE cases).

**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 a 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 might be sent by courier only.

4. **Are *non-infectious perishable* cultures (agar or 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). 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).

**EXAMPLE CASES**

Case A

The organism to be sent is non-infectious, not genetically engineered (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 the UPU Articles RE 2401 and RE 806 packaging requirements (also former European Standard EN 829 having a minimum strength of a triple packaging. There is no accepted packaging with less strength than EN 829. However, EN 829 will probably be withdrawn in order to avoid confusion with PI 650, which has similar quality). >> If not permitted by Postal Administrations, freight (courier service) must be used.

Case B

The organism to be sent is infectious but if exposure to it occurs 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, IATA DGR (see Addendum to the IATA DGR 46$^{th}$ Ed.). A Shipper's Declaration for Dangerous Goods is not required. The new Proper Shipping Name as given above can be used (alternatively to "Diagnostic specimens" or "Clinical specimens"). Shipment by airmail is usually prohibited; some national postal services may permit 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 is to be shipped as a Class 6.2 dangerous goods by freight, national postal mail is excluded, air mail is prohibited (IATA DGR 2.4). When shipping infectious substances of Category A, independently of the net weight, the UN Model Regulations apply for <u>all</u> modes of transport requiring a UN certified combination packaging system acc. to IATA Packing Instruction 602. The shipper is a trained person and is responsible for the consignment including all documents (IATA DGR 1.5). 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 (IATA DGR 8.1.6.11.3). Observe the IATA DGR Limitations chapter. Transport of these cultures is usually individual.

Case D

The organism to be sent is genetically engineered (GEM/GMO). The IATA DGR and other transport regulations distinguish between 2 kinds of GEMs: an infectious substance that is genetically engineered has to be shipped as >> UN 2814, UN 2900 (both Category A) or UN 3373, Category B, respectively (for the latter see Case B). Animals containing or being contaminated with GEMs or infectious substances, must not be transported by air unless exempted under IATA DGR 2.6.1. GEMs being not infectious substances but <u>capable of altering</u> 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: IATA Packing Instruction 913 applies; Class 9 label required (black and white stripes).

Case E

Carbon dioxide, solid, dry ice, is used for shipping an organism. >> Dry ice is classified as dangerous goods (Class 9, UN 1845) and has to be packed acc. to IATA Packing Instruction

904. Packaging systems for shipping UN 2814/UN 2900 or UN 3373 infectious substances together with dry ice are commercially available from several suppliers. Such packaging systems fulfil both packing requirements, for infectious substances and for dry ice and carry both dangerous goods labels and specification markings.

**SOME GENERAL HINTS FOR SAFE PACKAGING**

Petri dishes as primary receptacles should not be used for transport.
Screw caps, glass material and seals used for the purpose, as primary receptacle should be of good quality so that leakage is avoided during transport.
Only industrially available certified UN packaging systems are permitted, no other combinations.
When packaging is being re-used, it must not have any signs of any damage or previous leakage.

**Associated example materials as appropriate**

Labels as required (if not directly printed on outer packaging surface)
Shipper's declaration documents
Quarantine import permit
Information on categorisation of hazard group
Information sources
Images of packing materials and packages

**International Organisations**

***IATA***: the International Air Transport Association annually updates the Dangerous Goods Regulations (DGR) which are the legally binding basis for shippers and carriers of dangerous goods to be transported by air.

***ICAO***: the International Civil Aviation Organization Council uses the UN Model Regulations as the basis for its 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 Compendium of Information (constantly updated).

***WHO***: the World Health Organization defines the Risk Groups scheme for classification of biological substances and has published the Laboratory Biosafety Manual.

## Further Information

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| Canadian Transport | www.rural-gc.agr.ca/e4.1_canutec.html |
| EBIS | www.ivr.nl/ebis.html<br>www.ccohs.ca/products/database/tdg.html |
| European Commission DGVII – Transport | http://europa.en.int/en/comm/dg07/index.htm |
| Harmonisation of UN documents etc. | www.hazmat.dot.gov/rules |
| International Air Transport Association | www.IATA.org/cargo/dg<br>and www.IATA.org/cargo/dg/links.htm |
| International Civil Aviation Authority | http://hazmat.dot.gov/icao.htm<br>www.volpe.dot.gov/ohm/icao.htm<br>also www.cam.org/~icao/menu3.html |
| OECD - Harmonisation Documents | |
| Chemical programme | http://www.oecd.org/ehs |
| Classification and labelling | http://www.oecd.org/class |
| Chemical testing | http://www.oecd.org/test |
| Currently available test guidelenies | http://www.oecd.org/test/testlist |
| RID/ADR | http://hazmat.dot.gov/RIDADR.htm<br>www.dsidat.com/products/undisk7.htm<br>www.volpe.dot.gov/ohm/ridadr.htm |
| Transport – general | www.tci-transport.fr<br>www.hazmathelp.com/dotlink.htm<br>www.cefic.org |
| UN Model Regulations, Committee of Experts on the Transport of Dangerous Goods, Meetings agenda and minutes | www.unece.org/trans/danger/publi/unrec/rev13/ |
| Universal Postal Union | http://ibis.ib.upu.org<br>http://unicc/unece/trade/facil/upustr.htm |
| USA Dept of Transport's Office of Hazardous Materials Management | http://hazmat.dot.gov |

## Useful References


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European Parliament (2000) Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work. OJ No. L262, pp. 21-45 of 18.09.2000

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Technical Instructions for the Safe Transport of Dangerous Goods by Air. Doc 9284-AN/905. Council of ICAO, International Civil Aviation Organization

ADR Accord européen relatif au transport international des marchandises dangereuses par route. English version (2005). Economic Commission for Europe (ECE)