

New Transport Regulations for Infectious Substances as of January 2005

by Dr Christine Rohde

The intention of this information is to briefly inform all shippers of infectious substances on the changes set in force by the **United Nations Model Regulations for the Transport of Dangerous Goods** ("Orange Book"). The UN Sub-Committee of Experts on the Transport of Dangerous Goods, UNSCETDG, agreed on principal changes in the transport regulations for infectious substances, Class 6, Division 6.2. This UN expert group is the relevant international body responsible for defining the packaging and transport requirements of all kinds of dangerous goods. In 2003, WFCC received observer status to this Sub-Committee. The UN Model Regulations are governing packaging and shipping questions for all modes of transport world-wide (road, air, rail, waterways). Air transport plays the major role in case of international shipping of biological materials; therefore the respective **Dangerous Goods Regulations (DGR)** as implemented by the International Air Transport Association (**IATA**) are mentioned here repeatedly. For air transport, the **ICAO Technical Instructions** (ICAO TI, updates every two years) are the legal background whereas the annually updated IATA DGR are regarded as being a user-friendly, actual and reliable handbook for the shipper. It is recommended that all shippers of dangerous goods including infectious substances have access to the IATA DGR, which are available in several languages.

The announced changes appeared for the first time in the IATA DGR 2004 edition as Appendix I and have become effective in January 2005 as chapter 3.6.2 in the IATA DGR 2005 (46th edition). All senders of infectious substances are obliged to use these new regulations when they classify their biological material prior to shipments.

The principal change effective since 01.01.2005 is that the UN Model Regulations moved away from using the Risk Group allocations of microorganisms and that two categories for transport classification of infectious substances apply instead: Category A and Category B. Consequently, the Risk Groups which still play a fundamental role for handling during work with the organisms only play an indirect role for transport classification. The correct classification of dangerous goods or in this context of infectious substances is the very first decision-making step the responsible shipper has to perform before arranging all subsequent steps: choosing the correct packaging and the correct, fastest and safest carrier.

There are fundamental practical differences between the new shipping Category A and Category B: The UN Model Regulations have published an indicative examples list (not shown here) of infectious substances containing highly pathogenic viruses and bacteria classified in Risk Groups 3 and 4. This list is not exhaustive and new or emerging pathogens may be added to it, according to the definition of the criteria for inclusion in Category A (see below). Also, in cases of doubt as to whether or not an infectious substance

meets the criteria, it must be included in Category A. Infectious substances sent under Category A are UN 2814 (affecting humans) or UN 2900 (affecting animals). Such consignments underlie the same regulations, checking and handling procedures, the same documentation requirements and all strict dangerous goods requirements of the transportation chain as shippers of these UN numbers are used to apply, e.g. including the 24 hours emergency contact telephone number on the Shipper's Declaration form and the obligatory advance arrangements between shipper and recipient.

The definition of the new shipping Category A is given under 3.6.2.2.1, IATA DGR 2005:

“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.”

It is necessary to inform the reader of this information that well-known courier services licensed for transporting infectious substances have placed restrictions on the international transport of the new Category A, UN 2814/UN 2900, which seems comparable to a ban. The transport restrictions are so severe that shippers should have a closer look at the definitions and criteria prior to classification of the infectious substance to be transported:

Classification decisions

Does the definition of Category A apply and does the definition of the term culture apply? What are “high concentrations” in a (freeze-dried) culture compared to a diagnostic sample? Is a freeze-dried culture a true “culture”? The understanding of the *hazard* as mentioned in the definition of Category A excludes the definition of the Risk Group 2 so that it is recommended to classify case by case when organisms allocated to the Risk Group 2 are shipped. What are “diagnostic purposes”? Does it include reference or test strains? All these arguments together have to lead to a justified classification by the shipper who has the responsibility to consider and weigh all these possible hazards. It is recommended to look at the PQSR Committee report (please see WFCC web site).

The definition of the term “Cultures” is given under 3.6.2.1.3, IATA DGR 2005:

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

The definition of the new shipping Category B is given under 3.6.2.2.2, IATA DGR 2005:

“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 except that cultures, as defined in 3.6.2.1.3, must be assigned to UN 2814 or UN 2900, as appropriate.”

In case of shipments of Category B, UN 3373, diagnostic specimens, a clear transport deregulation has been verified: a Shipper’s Declaration form and a dangerous goods declaration form for road transport (ADR in Europe) are not required. The transport emergency card is not a must anymore. The regulatory bodies have introduced a modification towards a deregulation by introducing the new classification scheme including the new Category system and the new UN number 3373. But, it should be emphasized that

- It is still the shipper who is the responsible person for correct classification of the biological material, packaging, marking and labelling and documentation before offering a consignment for transport (IATA DGR 1.3, 46th ed.)
- The shipper has to be a trained person acc. to IATA DGR 1.5, 46th ed.. Recurrent training is required
- All kinds of infectious substances fall under the transport regulations for dangerous goods, although consignments containing infectious substances classified in Category B, UN 3373, sent for diagnostic purposes, are not accompanied by those documents required for Category A, UN 2814 or UN 2900 resp. (highly pathogenic dangerous microorganisms), their transport is deregulated.
- The correct choice of the required packaging (according to IATA Packing Instruction 650 or PI 602) is crucial. Even if PI 650 packagings are officially sufficient for Category B, UN 3373, PI 602 packagings offer more strength and stability during transport

Non-infectious biological materials:

It is important to note that the UN Model Regulations are NOT governing packaging and shipping of non-infectious biological materials where the definition of a dangerous good does not apply (usually per definition the Risk Group 1 microorganisms). Hence, such microorganisms are NOT regulated by the ICAO TI and IATA DGR. For such biological materials, still the regulations by the Universal Postal Union (UPU) for transport by postal mail services apply. Of course, such substances can also be sent by courier in case national postal services don’t permit mail transport of biological materials or if there are other reasons for choosing transport by courier systems. The principal difference between postal mail and courier transport is that the courier transport takes care of the individual consignment and offers tracking of each consignment at any time whereas this is not possible by usual postal mail. Again, it should be mentioned here that if postal mail transport is permitted in an individual case, it is advisable to use registered letter mail instead of normal letter mail. Non-registered letter mail may be used when

freeze-dried harmless biological material is shipped (note: postal parcels are not permitted for transport of any biological material). The Postal Convention (Letter Post Compendium, UPU) contains several Articles describing the international requirements for packing biological materials when sent by Postal mail. These Articles are RE 412, RE 413 and RE 207. Consignments transported by courier services are called freight; they are accompanied by a special document (Waybill).

Whenever microorganisms are shipped and independently of the mode of transport: the **triple packaging system** applies without exemption:

- **Primary receptacle(s)** which have to be leakproof in case of liquid substances
- **Secondary packaging** which has to be leakproof in case of liquid substances
- Rigid **outer packaging** (for better handling, for further protection and for carrying documents, addresses and labels)

A big variety of packagings for all kinds of biological materials (whether they are harmless environmental isolates, diagnostic specimens of Category B or dangerous pathogens of Category A) are offered by specialised manufacturers.