International Regulations for the Safe Transport of Biological Materials

Prepared by the Federal Republic of Germany

1. Whether it is compliance with the law or the duty of a caring employer, there are numerous basic requirements to establish a safe workplace in the biological laboratory, it is the hallmark of technical excellence. There is complex biolegislation in place in order to verify

- adequate assessment of risks
- provision of control measures
- provision of health and safety information
- appropriate training
- establishment of record systems to allow safety audits
- implementation of good working procedures

2. There is no doubt about safety requirements in the laboratory or in a production facility. But what about packaging and shipping?

3. All kinds of biological materials/living cultures are travelling around the world: for R & D purposes, as reference material for science and biotechnology, for testing and application for medical or academic purposes. Progress in infectious diseases research and better control involves the respective test strains and it is essential that authentic cultures are supplied by the recognised culture collections and biological resource centres (BRCs) to recipients who are authorised to work with them. Hence, it is the aim of the BRCs to guarantee a bonafide supply worldwide if all precautionary steps have been taken so that cultures cannot fall into wrong hands. The same also has to be respected when microorganisms are transferred between other facilities which posses licenses to handle microorganisms.

4. What is in between the shipper and the recipient of a microorganism?
It is the transportation chain involving persons not being trained to work with microorganisms. This catchword clearly demonstrates there is a step-by-step chain which has to work in a smooth and safe manner. In this context, those living (micro) organisms have to be addressed which definitely or possibly bear the risk of either being infectious to humans or animals, being toxin producers or being capable to alter other organisms in the environment (see definition of
genetically modified microorganisms). In terms of international packaging and shipping regulations, all such organisms are defined as **dangerous goods** and the respective packaging and transport regulations fully apply. All shippers wishing to offer such a consignment for transport have previously to adhere to several other laws and regulations: there are export regulations in place (National Export Offices/Authorities), import permits for import of a certain microorganism might be required (National Quarantine Authorities) and individual working permits might be requested. Also, stringent rules exist for export/import of some animal or plant pathogens. Correct packaging and shipping is the very final step which requires a lot of care and sound knowledge on the complex regulatory background.

5. Over the past decade, BRCs have observed that quarantine, postal and packaging regulations become more rigorous the more they are ignored. However, it is a significant difference between working with a microorganism in a laboratory and handling a consignment containing a microorganism.

6. The WHO Risk Group definitions had been considered as the only possible basis to define the hazards of microorganisms during transport and consequently led to a clear classification: there are biological substances which are **dangerous goods** („dg“) (UN Class 6, Division 6.2) and such which are not regulated (not dangerous). This system has now been modified (IATA Dangerous Goods Regulations 44th ed., 2003) in case of the diagnostic specimens but still applies in case of the „cultured microorganisms“ which have gone through a laboratory process in order to produce a pure culture. The allocation of organisms to a Risk Group can vary from country to country or from region to region (e.g. Europe and USA) and is not harmonised on a world-wide basis, due to different health standards, precautionary methods (vaccination) and other aspects. This makes obvious that international transport of infectious substances sometimes bears a difficulty for the shippers.

7. It is fundamental for all shippers in all individual cases of shipments of biological materials to be certain about the dg status. As there are also other categories of biological materials besides cultured microorganisms which are dg:
   - several groups/definitions of genetically modified microorganisms and organisms
   - biological products
   - medical wastes
   it is impossible to explain the details in this context.

8. The responsibilities placed on the shipper and the potential consequences of failure to follow legislation are as follows: the shipper is responsible for the selection of adequate packaging systems, for the collaboration with the carrier/courier and for all advance arrangements as required (especially in case of air transport) so that the shipment reaches its destination fast and safely. Fortunately, there is world-wide harmonization with respect to packaging and shipping requirements (once the material to be shipped is classified!): the **Regulatory Cascade** is headed by the United Nations Expert Committees for the transport of dangerous goods. All modes of transport (road, rail, air, sea, waterways) have to implement the regulations. A typical triple packaging system which resembles an UN-certified combination packaging for Division 6.2 microorganisms is required. This guarantees a very high safety being the only barrier between the material inside and the person handling the consignment and is commercially available through world-wide distributors.
9. The German Collection of Microorganisms and Cell Cultures often focus very much on the IATA DGR as 1) air transport has developed to an outstanding role nowadays and 2) also because the IATA DGR are extremely user-friendly and clear. The third reason is that the IATA DGR are the most stringent rules so that shippers are on the safe side if they strictly follow them.

10. Culture collections (BRCs) are often asked for help in terms of „Step-by-step shipping instructions“. However, the general or „job-specific“ training courses cannot be replaced by instructions or books. The IATA DGR are constantly updated (annual editions) and shippers are required to refresh their knowledge every second year if they are transporting dg by air. The awareness of correct transport of biological materials has only quite slowly come into being. Certainly, all institutions should be on the safe side as penalties can be very high.

11. The World Federation for Culture Collections (WFCC) Committee on Postal, Quarantine and Safety Regulations disseminates information on the ever-changing rules to its members and to all others in an attempt to reduce common mistakes. A much wider audience is needed.