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**COMMITTEE OF EXPERTS ON THE TRANSPORT OF
DANGEROUS GOODS AND ON THE GLOBALLY
HARMONIZED SYSTEM OF CLASSIFICATION
AND LABELLING OF CHEMICALS**

Sub-Committee of Experts on the
Transport of Dangerous Goods

Twenty-fifth session, 5-14 July 2004
Item 6 of the provisional agenda

LISTING, CLASSIFICATION AND PACKING

Modification of shipping regulations for biological materials
classified in Risk Group 2/Category B Cultures

Transmitted by the World Federation for Culture Collections (WFCC)

Background

The World Health Organization Risk Group definition scheme sets the basis for the Risk Group allocation of all kinds of microorganisms and is intended to protect personnel working with biological agents in the laboratory. Classification of microorganisms with respect to health and safety at the work place was the basic concern.

Considering the infectivity and pathogenicity of Risk Group 2 organisms and the availability of preventive and therapeutic measures the risk is low for employees and the public. Microorganisms classified in Risk Group 2 by the European Council Directive 2000/54/EEC of September 2000 (amending 90/679/EEC) include a high number of described species known to live as commensals e.g. on the human oral mucosa or which are generally wide-spread in the environment. There are countless examples for rather harmless organisms of Risk Group 2 which may be regarded as opportunistic or low grade pathogens being documented only in nosocomial infections. Without doubt, organisms meeting the definition of the new Division 6.2 Category B for shipping purposes fall into the Risk Group 2.

Role of the WFCC

Correct packaging and shipping of biological materials is a matter of justified concern. For many years this kind of international bio-legislation has been one of the main topics of discussion for the WFCC (World Federation for Culture Collections) Committee dedicated to questions and international or regional developments on Postal, Quarantine and Safety Regulations. The WFCC, founded in 1963, is a multidisciplinary Commission of the International Union of Biological Sciences (IUBS) and since the separation of the International Union of Microbiological Societies (IUMS) from IUBS in 1979 has

operated as an inter-union Commission. It seeks to promote and foster activities that support the interests of Biological Resource Centres and the scientific community in the ex situ conservation and utilisation of the biological diversity. The WFCC represents more than 750 microbiologists including some of the worlds leading scientists and has published guidelines for the establishment and operation of Biological Resource Centres and has several standing committees. The Committee on Postal, Quarantine and Safety Regulations (PQSR) has contributed considerably to the distribution of information and consequently to a raised awareness in this area and functions as an information forum. There are currently eleven members of different nations in this Committee, all are experienced scientists working in renowned culture collections/biological resource centres. They have hands on practical knowledge of the implementation of safety measures and bio-legislation. WFCC and its Committees present information via <http://www.wfcc.info>.

WFCC proposal

The WFCC PQSR Committee proposes a modification of the UN Model Regulations with respect to the shipping of Risk Group 2 cultures/Category B cultures as follows:

- *that such organisms can be transported according to the same requirements as diagnostic/clinical specimens, UN 3373 (P 650);*
- *under 2.6.3.2.2.2, UN Model Regulations, Category B definition, the following wording should be deleted: ... "except that cultures, as defined in 2.6.3.1.3, shall be assigned to UN 2814 or UN 2900 as appropriate.";*
- *we suggest to use the Proper Shipping Name "Infectious substance, Category B" (or vice versa).*

As a precondition of adopting this WFCC proposal, it is important to make a realistic comparison of potential risk during laboratory work and during transport. Both situations should be carefully balanced when the regulations are reviewed as it is apparent that the risk associated with safely packaged cultures in transit is significantly lower than the risk when working with them. It is also a fact that a perceived risk in contrast to a real risk plays a role as an emotional aspect when transporting infectious substances.

If a Risk Group 2/Category B organism is properly packed and offered for transport in a high quality UN packaging system according to packing instruction P650 (for diagnostic/clinical specimens, UN 3373), such a consignment is as safe as under packing instruction P602 (for infectious substances meeting the definition of Category A). Shipments containing known species are in most cases not more dangerous than shipments containing diagnostic specimens with an unknown pathogenic potential. Furthermore, scientists or Biological Resource Centres are often exchanging small amounts of freeze-dried microorganisms being in a physiological inactive form. They usually bear *a priori* a lower risk than diagnostic specimens. The former are often laboratory derivatives which need a preculturing step, the latter are natural cultures directly isolated from patients.

The WFCC Committee endorses such a new model for international shipping of microorganisms in which realistic simplifications, especially concerning administrative expenditure, will lead to enhancing and strengthening the willingness to adhere to the laws while the transport itself would by no means become less safe. In contrast, the current complicated and extraordinarily expensive shipping-conditions for Risk Group 2 organisms result in serious impediments to microbiological research. Shippers are often not adhering to any regulation and use undeclared letter mail.

Transport of microorganisms falling under the Risk Group 3 or 4 definitions, is not subject to the discussions in this proposal as such pathogens are without doubt dangerous goods.
