

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
Geneva, 5-14 July 2004
Item 6 of the provisional agenda

LISTING, CLASSIFICATION AND PACKING

Revisions to ST/SG/AC.10/C.3/2004/51

Transmitted by the World Federation for Culture Collections (WFCC)

Background

The WFCC recognizes that the proposal submitted in ST/SG/AC.10/C.3/2004/51 may not have clearly articulated the change to the UN Model Regulations that the WFCC is proposing.

Consequently, it is hoped that this revision will clarify the WFCC's intent.

The WFCC recognizes that laboratories in hospitals, diagnostic and research facilities handle samples of human, animal or other biological material and cultures derived from them. These are classified according to the World Health Organization's Risk Group classification criteria. The Risk Group criteria are based on the risk posed in the laboratory and determine biosafety levels, practices and equipment for laboratory work. If samples or cultures are to be transported, then the laboratory, hospital or other facility must comply with transport requirements including classification and packaging. In order to better reflect the risks during transport, the UN Model Regulations have moved away from the concept of Risk Groups. The UN Model Regulations require cultures classified in Category B to be transported as Category A under UN numbers 2814 or 2900. However, if shipment of such cultures is intended for diagnostic or clinical purposes, transport as UN 3373 is permitted.

Category A includes infectious substances which are transported in a form that, when exposure to them occurs, are capable of causing permanent disability, life-threatening or fatal disease to humans or animals. Microorganisms included in Category A are listed in paragraph 2.6.3.2.2.1 of the UN Model Regulations. The category includes microorganisms which may be classified in different Risk Groups in different regions or countries, but primarily includes Risk Group 3 or 4 organisms.

Category B includes **infectious** substances which do not meet the criteria for inclusion in Category A. However, such cultures are to be transported as Category A under UN numbers 2814 or 2900 if intended for investigational scientific laboratory purposes.

WFCC proposal

In ST/SG/AC.10/C.3/2004/51 WFCC stated that cultures of Category B Risk Group 2 microorganisms pose a low risk for employees in laboratory work and for the public for transport purposes given their low level of infectivity and pathogenicity and the availability of preventive and therapeutic measures (see Risk Group 2 definitions by several international Authorities below).

Consequently, the WFCC believes that cultures of Category B Risk Group 2 substances for laboratory or investigational work can be safely transported as Category B under UN3373.

The WFCC proposes modifications to the UN Model Regulations with respect to the transport of Risk Group 2 cultures as follows:

- * that 2.6.3.1.3, the cultures (laboratory stocks) definition be re-worded as follows:

“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, clinical and investigational purposes like laboratory assay, quality control or reference purposes”

- * that, given the low risk such organisms pose even in cultured form, they can be safely transported as Category B, UN 3373, in packaging that is in compliance with P650;

- * that 2.6.3.2.2.2, the Category B definition, be re-worded as follows:

“2.6.3.2.2.2 Category B: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B shall be assigned to UN 3373. Cultures, as defined in 2.6.3.1.3, that contain Category B infectious substances shall be assigned to UN 2814 or UN 2900, as appropriate, except that substances classified for the purposes of laboratory work as Risk Group 2, may be transported as Category B, UN 3373.”

NOTE: The proper shipping name of UN 3373 should be “DIAGNOSTIC SPECIMENS” or “CLINICAL SPECIMENS” or “BIOLOGICAL CULTURES, Category B”.

As stated in ST/SG/AC.10/C.3/2004/51, 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 transport is significantly lower than the risk when working with them. The WFCC recognizes that a perceived risk in contrast to a real risk plays a role as an emotional aspect when transporting infectious substances.

The members of WFCC endorse the view that a Risk Group 2 culture marked and packaged in accordance with P650 is as safe for transport as compliance with the requirements for Category A substances.

Risk Group 2 definitions by different international authorities:

European Economic Community:

“Group 2 biological agent means one that can cause human disease and might be a hazard to workers; it is unlikely to spread to the community; there is usually effective prophylaxis or treatment available.”

NIH Guidelines:

“Risk Group 2 agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.”

Canadian Laboratory Biosafety Guidelines:

“Risk Group 2 (moderate individual risk, limited community risk) A pathogen that can cause human or animal disease but under normal circumstances, is unlikely to be a serious hazard to healthy laboratory workers, the community, livestock, or the environment. Laboratory exposures rarely cause infection leading to serious disease, effective treatment and preventive measures are available and the risk of spread is limited.”

CDC/NIH Biosafety in Microbiological and Biomedical Laboratories:

“Biosafety Level 2 is similar to Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment.”

WHO Laboratory Biosafety Manual:

“Risk Group 2 (moderate individual risk, low community risk)

A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited. ”
