
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-eighth session
Geneva, 28 November – 7 December 2005
Item 6 of the provisional agenda

MISCELLANEOUS PROPOSALS FOR AMENDMENTS TO THE MODEL REGULATIONS ON THE TRANSPORT OF DANGEROUS GOODS

Infectious substances: Definition of cultures

Transmitted by the expert from Germany

Background

At the meeting of the UN Sub-Committee (UNSCETDG) in July 2002, a definition of “cultures” as a new and independent category of infectious substances was included for the first time in the UN Model Regulations in the framework of the restructuring of class 6.2. In the definition (document ST/SC/AC.10/C.3/2002/16) “*Cultures* are the result of a process by which pathogens may be amplified or propagated to generate high concentrations not normally found in nature, thereby increasing the risk of infection when exposure to them occurs” microbiological cultures of any kind and of all pathogenic micro-organisms (categories A and B) were generally assigned to category A and thus to UN numbers 2814 or 2900.

The definition and classification of cultures, which has been amended several times, has again and again led to misunderstandings, discussions and even international protests (World Federation of Culture Collections, American Microbiological Society, Standing Committee of European Doctors and others).

This is mainly due to the fact that, up to now, microbiological cultures have been wrongly defined in any of the definitions as the result of a process by which micro-organisms are “intentionally propagated” in order to generate high concentrations or a large number of micro-organisms. In accordance with the international state of research in microbiology, this however at best applies to mass cultures created for industrial and specific research purposes. Moreover, these cultures are in most cases not carried via the public transport infrastructure so that the definition is not relevant to practice in this respect either.

In practice, the cultures carried almost exclusively are “cultures used for diagnostic purposes”. As a rule, a volume of 10 ml is sufficient for this purpose.

Furthermore, it has not sufficiently been taken into account so far that

1. cultures which have been isolated from diagnostic patient specimens and which are dispatched for the purpose of further diagnosis as a rule do not contain more pathogenic micro-organisms than may be contained in the relevant patient specimens themselves;

2. even if the concentration of pathogens (agents) is higher in individual cases, the likeliness to contract an infection (risk of infection) through contact with diagnostic cultures in the case of damage in transit is not significantly higher than in the case of contact with infectious patient specimens since these specimens (e.g. *shigella dysenteriae* in stool specimens) may already contain a sufficient number of pathogens capable of causing an infection (infective dose);
3. even in cases where a damage in transit with a culture that may, in individual cases, contain a larger amount of pathogenic micro-organisms of category B (e.g. salmonella) or contain such micro-organisms as are listed in the indicative table in 2.6.3.2.2.1 together with the additional note "cultures only" (e.g. former hazard group 3 such as *Escherichia coli*, verotoxigenic) leads to an infection, these pathogens - in contrast to lassa or ebola viruses which on principle cause life-threatening or fatal diseases and are therefore rightly classified under category A in accordance with the definition - will in no case cause a disease which is completely different from a qualitative point of view;
4. there are different kinds and forms of microbiological cultures which, depending on the purpose for which they are used, vary widely in concentration and quantity of micro-organisms carried and therefore have to be evaluated differently.

Germany holds the view that in order to avoid further misunderstandings and discussions, the definition of microbiological cultures should be redrafted for the 15th edition of the Model Regulations on the basis of the international state of medical science.

Proposal 1

Germany requests the UNSCETDG to consider these aspects and proposes to replace the definition in 2.6.3.1.3 with the following wording:

Microbiological cultures are the result of the selective propagation (cultivation) of viable micro-organisms. They are differentiated as:

a) Cultures used for diagnostic purposes

Diagnostic cultures contain viable micro-organisms which are selectively isolated from diagnostic patient specimens in *small quantities*, i.e. in quantities usually corresponding to those of patient specimens. They are used to obtain pure strain isolates for their identification, determination of antibiotic resistance, epidemiological investigations, reference typing or for stock culture collection.

The volume of tubes for diagnostic cultures usually will not exceed 10 ml.

b) Cultures for industrial or scientific use

Industrial cultures contain viable micro-organisms which significantly exceeded microbial contents of diagnostic cultures, with the aim of *mass production* for industrial or scientific use.

Justification

Maintaining the current definition of cultures would, if certain pathogens were classified under category A, result in an unacceptable obstruction of both the medically justifiable treatment of patients and the national and international monitoring of infectious diseases which is required for public health and epidemiological reasons.

The proposed definition, however, takes account of the latest scientific developments in microbiology and medicine. It differentiates (the sometimes large quantities of) cultures used for diagnostic purposes, which are transported in many countries, from industrial mass cultures which are only carried in exceptional cases.

In this way, it is possible to carry out a separate evaluation of the required safety standards for packaging and transport. This differentiated evaluation makes it possible to properly classify cultures used for diagnostic purposes, avoid “over-regulation” and transport such cultures under conditions which are appropriate to the moderate risk of infection.

Proposal 2

It is proposed to replace the supplementary information “cultures only” in the indicative list in 2.6.3.2.2.1 (category A) for the micro-organisms

- *Escherichia coli, verotoxigenic* (cultures only)
- *Mycobacterium tuberculosis* (cultures only)
- *Shigella dysenteriae type 1* (cultures only)

with “cultures for industrial and scientific use only”, so that the wording reads as follows:

- *Escherichia coli, verotoxigenic* (cultures for industrial or scientific use only)
- *Mycobacterium tuberculosis* (cultures for industrial or scientific use only)
- *Shigella dysenteriae type 1* (cultures for industrial or scientific use only).

Justification

Pathogens which are stated in the indicative list in 2.6.3.2.2.1 and particularly often concerned by the above-mentioned “over-regulation” are *Escherichia coli* (verotoxigenic), *mycobacterium tuberculosis* and *shigella dysenteriae type 1*, and therefore, they are of particular diagnostic and epidemiological importance. A distinctive example of this is the threat posed by tuberculosis which is spreading from Eastern Europe to Central and Western Europe. Therefore, a low-cost transport of diagnostic cultures of these pathogens, which is appropriate to the risk of infection and carried out under the less stringent conditions of packing instruction P650, is of urgent multi-national interest in terms of health policy and the control of these infectious diseases.
