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HARMONIZATION WITH THE UNITED NATIONS MODEL REGULATIONS ON THE TRANSPORT OF DANGEROUS GOODS

Class 6.2: Classification of cultures of risk group 3 for diagnostic purposes (Indicative list of Category A substances)

Transmitted by the Government of Germany*

The secretariat has received from the Central Office for International Carriage by Rail (OCTI) the proposal reproduced below.

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SUMMARY

Executive summary: The indicative list in paragraph 2.2.62.1.4.1 of RID/ADR also includes pathogens according to annex III of Directive 2000/54/EC that are assigned to Category A in the form of cultures only. This proposal sets out the reason why this classification for the carriage of cultures for diagnostic purposes is erroneous from the safety standpoint. Justification is also provided for the reason in the case of certain selected pathogens for particular interest in terms of health policy in easier carriage in respect of UN No. 3373 (Category B).

Action to be taken: Deletion from the Category A indicative list of the micro-organisms:

- Escherichia coli (verotoxigenic)
- Mycobacterium tuberculosis
- Shigella dysenteriae

Related documents: TRANS/WP.15/AC.1/2005/42/Add.1-OCTI/RID/GT-III/2005/42/Add.1 and the Directive of the European Parliament and of the Council on the protection of workers from risks related to exposure to biological agents at work (2000/54/EC).

Scientific aspects

(a) Pathogenic nature and transmissibility

Category A infectious substances (pathogens) are defined as substances capable of causing life-threatening or fatal disease to humans. This is particularly the case of substances assigned in *all* forms to Category A in accordance with the list of examples of paragraph 2.2.62.1.4 of RID/ADR.

These cases exclusively concern particular viruses. From the infectious point of view, they are characterized by an extremely low dose of infection (theoretically, only a few particles of virus) and very easy transmissibility, also from person to person. Because of the danger of propagation, they not only represent a high risk to individuals but also to the community. There is normally no effective treatment for the diseases they lead to which means that the outcome is generally fatal (e.g. haemorrhagic fever caused by the Ebola, Lassa or Marburg viruses).

All the viruses assigned to group 4 of annex III of the EC Directive are part of this Category A group.

The above properties do not, however, apply to the bacterial pathogens also included in the list of examples in paragraph 2.2.62.1.4.1, which are only assigned to Category A according to the definition in paragraph 2.2.62.1.3 (intentional generation) in the form of cultures. Generally speaking, these substances do not cause life-threatening diseases in humans. Their assignment to Category A in the form of cultures by the United Nations Sub-Committee of Experts was justified by the fact that in the event of physical contact (exposure) following

leakage from the protective packaging, e.g. as the result of an incident during carriage, there is an increased risk of infection compared with diagnostic specimens which are assigned to Category B. This justification, however, is not applicable to cultures of bacterial agents for diagnostic purposes. First and foremost it should be noted that cultures for diagnostic purposes are not used to generate bacteria but only to keep them alive during carriage in order to be able to perform further analyses so that a diagnosis can be made. The substance content is consequently low, and often less than the content of the specimens from the original patients. The question of ascertaining whether these cultures can cause an infection depends on numerous additional factors.

Thus Mycobacterium tuberculosis has to be absorbed by the respiratory organs, while Escherichia coli (verotoxigenic) and Shigella dysenteriae have to be absorbed by the stomach/intestine, but not through the skin. The risk of infection from these bacteria is therefore unlikely, even in the event of physical contact, for example, by the emergency services following an accident during carriage in which the protective packaging is destroyed.

It is, however, of decisive importance to note that, even in the case of an infection resulting from the pathogenic properties of the above bacteria, there is *no* question of life-threatening or normally fatal diseases, unlike the viruses previously mentioned, within the meaning of paragraph 2.2.62.1.4.1. Appropriate antibacterial therapies for the various types of pathogens do exist. The two criteria in principle differentiate these bacterial pathogens - also when they are in culture form - from the viruses cited in the list of examples, all forms of which are assigned to Category A.

(b) Importance of cultures for medical diagnosis

In many countries small isolated amounts of cultures from patients' specimens are sent to specialized laboratories for diagnostic purposes. The aim of these special examinations is to detect the particular properties of the isolated pathogen, such as resistance to antibiotics. Knowledge of these properties is important for treating patients. Another aim of special culture diagnosis is to perform epidemiological tests to detect, anticipate and prevent the spread of infectious diseases.

In Germany, as in other European countries, there is a legal obligation in the interest of the community to monitor and prevent diseases also caused by bacterial agents appearing in the indicative list with the proviso "cultures only". Escherichia coli (verotoxigenic), Mycobacterium tuberculosis and Shigella dysenteriae are particularly frequent and consequently of extreme epidemiological importance. For these pathogens, cheap and easy carriage in the form of cultures for diagnostic purposes (isolated from patients' specimens) is therefore absolutely necessary.

In view of the deletion of the exception for "cultures for diagnostic purposes" decided by the United Nations Sub-Committee of Experts for the fourteenth edition of the United Nations Recommendations, all pathogens in the indicative list carrying the addition "cultures only" or in the form of these cultures for diagnostic purposes should be generally assigned to UN No. 2814 if included in RID/ADR 2007. It may be regarded as certain that an increase in the costs of packing (packing instruction P 620) and transporting these cultures and the difficulties arising

from security requirements (chap. 1.10) with reference to UN No. 2814 will significantly hinder the monitoring and prevention of the infectious diseases in question. Since infectious diseases are not restricted by State borders, this situation is unacceptable, also as a matter of international interests. A notable example is the danger of tuberculosis which is spreading from Eastern Europe towards Central and Western Europe.

Proposal

Deletion of the following micro-organisms from the list of examples in paragraph 2.2.62.1.4.1 of RID/ADR:

- Escherichia coli (verotoxigenic) (cultures only);
- Mycobacterium tuberculosis (cultures only);
- Shigella dysenteriae type I (cultures only).

Justification

By their deletion from the indicative list for Category A, the cultures of the above-mentioned pathogens - like the patients' specimens from which they were isolated - are assigned to Category B (UN No. 3373) of RID/ADR. The application of packing instruction P 650, which from the standpoint of safety is appropriate to their pathogenic nature and the relatively low risk of transmission is thus made possible, and results in the easing of conditions of carriage in European land transport. The conditions of carriage thus eased are in keeping with the public interest in preventing the international spread of infectious diseases.

Impact on safety

There is no negative impact on safety, since the carriage of cultures of the above-mentioned pathogens in safe packagings in accordance with packing instruction P 650 - as justified in (a) - does not involve a greater risk of infection than the carriage of patients' specimens in accordance with the same packing instruction. Packagings in accordance with packing instruction P 620 would not therefore provide increased safety. Consequently, their use for this purpose is not considered necessary.

Feasibility and applicability

No problems have been detected.
