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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

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Item 7 of the provisional agenda

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

Infectious substances

Transmitted by the Standing Committee of European Doctors (CP)

Background

ST/SG/AC.10/C.3/2004/51 transmitted by the World Federation for Culture Collection (WFCC); ST/SG/AC.10/C.3/2004/52 transmitted by the World Organisation for Animal Health (OIE); ST/SG/AC.10/C.3/2004/61 transmitted by the Netherlands; ST/SG/AC.10/C.3/2004/62 transmitted by Canada; ST/SG/AC.10/C.3/2004/73 transmitted by the International Civil Aviation Organisation (ICAO); UN/SCETDG/25/INF.29 transmitted by WFCC; UN/SCETDG/25/INF.35 transmitted by IATA; UN/SCETDG/25/INF.43 transmitted from the Joint Aviation Authorities (JAA) Dangerous Goods Study Group transmitted by the United Kingdom; UN/SCETDG/25/INF.50 transmitted by ICAO; UN/SCETDG/25/INF.60 from the Swiss Federal Roads Authority; UN/SCETDG/25/INF.62 transmitted by the Secretariat and UN/SCETDG/25/INF.79 transmitted by the World Health Organisation (WHO).

A common tenor of nearly all these papers is that the current classification and the resulting requirements for transporting “infectious substances” will probably cause more confusion than security. CP shares this view and therefore tries to contribute the following comments and proposals for clarification:

Comments (part I)

I. Common concern of all papers is to protect all persons directly involved in the transport of goods from any risk of infection.

II. A common intention is to establish definitions and recommendations which are reliable, practical and clear enough to avoid misinterpretation and handling-faults.

III. One reason for the current confusion is the fact that for risk assessment a classification of microorganisms is in use which was developped for a completely different purpose (see UN/SCETDG/25/INF.29!) and therefore inevitable inconsistencies must be the result.

IV. Another reason for the current confusion is the wrong supposition that “healthy-looking people” are free of microorganisms classified in Risk Group 2 or 3!

V. Furthermore we still are using a definition of "Infectious substances" (see UN/SCETDG/25/INF.62 Annex I 2.6.3.1.1) which is all but helpful.

Therefore CP tries to contribute to clarifying the matter of dispute by offering the following proposals.

Proposals

(I) Diagnostic specimen should be subdivided in the following groups:

1. Specimen from human individuals without any suspicion of an infectious disease and without known infectivity.

2. Specimen from human individuals with suspected and / or known infectious disease / infectivity …
   a) … with the probability / suspicion of active Category-A-microorganisms
   b) … with the probability / suspicion of active Category-B-microorganisms
   c) … without the probability / suspicion of active microorganisms

3. Specimen from environmental sources …
   a) … with the probability / suspicion of active Category-A-microorganisms
   b) … with the probability / suspicion of active Category-B-microorganisms
   c) … without the probability / suspicion of active microorganisms

4. Cultures …
   a) … of Category-A-microorganisms
   b) … of Category-B-microorganisms

Additional explanation:

Microorganisms are ubiquitous, not only microorganisms classified in Risk Group 1!

Human individuals live in symbiosis with microorganisms essential for life because of several reasons:

a) the microorganisms colonising skin and mucous membranes are an essential part of the human physiological defence system against pathogenic microorganisms (most of these microbes are classified in Risk Group 2!)
b) scientific data have proven an increased risk for developing allergies when children grow up in a "hygienic" environment. which means let children play in nature to have early and close contact with all kind of microorganisms (classified in Risk Group 2!)
c) more than 40 different species of microbes are colonising our oral cavity, in our gut we are harbouring about 10^{11}(!) microorganisms per gram feces (including Risk Group 2!)

WFCC therefore stresses correctly that "… the infectivity and pathogenicity of Risk Group 2 organisms … is low for employees and the public." (ST/SG/AC.10/C.3/2004/51) and some of the papers mentioned point out, that goods with infectious substances in concentrations encountered naturally represent no significant risk!

However, we can not postulate, that healthy appearing individuals are always free of any infectivity (see also UN/SCETDG/25/INF.79) but contrary to the WHO, CP emphasizes that this is a risk also classified as "encountered naturally".

Therefore we suggest the following regulations

(II) Goods grouped in 1., 2c),and 3c) according to our proposal (I) are not subject of these regulations

(III) Goods grouped in 2a), 3a) and 4a) according to our proposal (I) have to be shipped in P 620 packing

(IV) Goods grouped in 2b), 3b) and 4b) according to our proposal (I) are not subject of these regulations

(V) Cultures of Group-A-microorganisms have to be shipped in P 620 packing

(VI) Cultures of Group-B-microorganisms have to be shipped in P 650 packing

Additional explanation:

The task of this subcommittee is to regulate the transport of dangerous goods. To regulate the transport of goods without elevated (=significant) risk is not subject of this subcommittee, therefore, goods grouped according our proposal (II)and (IV) have to be exempt from infectious substance transport regulations.

Nevertheless, CP stresses the fact, that these goods, if it are specimen taken from individuals for diagnostic purposes have to be packed in a way to guarantee a safe and undamaged transport to the addressee (laboratory, reference institution). This is obligatory because of quality assurance for diagnostic procedures and diagnostic results and has to be regulated by other (national? medical?) authorities. Because the requirements are similar to the P 650 a slightly modified or even unmodified packing instructon is required, but without additional administrative requirements.

Cultures of Category-B microorganisms are in majority cultures of facultative pathogenic organisms and mostly cultivated from healthcare-aquired infections. These organisms – even when in elevated numbers - do not threaten healthy individuals (see also ST/SG/AC.10/C.3/2004/51) and in logical consequence are also not subject of this regulation. Nevertheless CP could agree with a P 650-packaging-requirement for these cultures.

Comments (part II) …

… to ST/SG/AC.10/C.3/2004/73 (ICAO):

Proposal 2: the packaging is composed of three parts: the inner vial, containing the specimen (fluid or pus), the second packaging, which is normally a "rigid"one, and the outer packaging, which can be a card-board box or an envelope as well. Mainly laminated envelopes offer a much better protection against soaking (rain) than a normal card-board box . A rigid outer packaging therefore should not be required.

Proposal 6: In case of limiting quantities it should be agreed on that the amount of material relates to the specimen only!

… to UN/SCETDG/25/INF.79 (WHO):

Definition of culture: We agree to delete special provision 319, but do not agree with the proposed change of 2.6.3.1.3 because there was a long discussion resulting in the common adoption to make a difference between "intentionally propagation" for industrial purpose and for diagnostic purpose (of course only for Category-B organisms!)

If the new 2.6.3.1.4 will be adopted, the following should be added: " …. independently of the transport medium" (the reason for that is to avoid discussion about the question whether a commercial blood culture-bottle - which is only the adequate transport medium – will be assigned to the category "culture" instead of "diagnostic specimen".

Exemptions: We support the endeavour to clarify the criteria to define exemptions. One reason for the current confusions is the fact of missing clear definitions of some terms used. This could, however, be the case as well for the suggested phrase "… in levels that pose a health risk …". This underlines a key-problem: the risk does not only depend on the number of organisms but also on their virulence which can differ from strain to strain among one spcies and – the most important aspect for our task – on the way of transmission! Here an example:

Mycobacterium tuberculosis belongs to Risk Group 3**, cultures even to Category A!

"**" means, the risk is reduced because airborne transmission is very unlikely. Why are cultures category A? Which way of transmission is postulated? The only alternative mode of transmission for TB would be the oral ingestion – very, very unlikely in case of a transport accident! The reason, why Mycobacterium tuberculosis was classified to Risk Group 3 was the significant risk while working in the laboratory with the liquid enrichment media because of resulting aerosols – a real risk as we know from infected technicians in microbiological laboratories. But outside a laboratory? A scientific paper describes the case of a young infant found infected with tuberculosis. None of his playmates in the kindergarden were positive, nor his brothers and sisters sharing the bed-room with him nor his parents! The only one positive for TB was the old grandfather who played with him in the afternoon while the parents were at work.

That means there was a long and close contact required with exposition to a high dosis of microorganisms together with the still immature immun-system of the young little child to become infected.

… to UN/SCETDG/25/INF.43 (JAA):

With this in mind the fear of any microorganisms as shown in this paper is incomprehensible. If "infectious substances in Category A or B are not permitted for transport in carry-on or checked baggage and must not be carried on the person" (p. 6) than all planes have to fly without passengers, because every passenger carries infectious substances Category B on his skin and mucous membranes! To transport microorganisms "in checked baggage" ore even in carry-on baggage is praxis among microbiologists and there is no provable rationale for such a requirement – except the current fear of terrorism in some countries after 9/11.

… to UN/SCETDG/25/INF.62 (Health-Care Waste; note by the secretariat):

Some years ago an analysis of different types of waste (health-care-waste from a) operating theatre b) isolation ward for patients with infectious diseases c) normal ward was compared with d) normal household waste) carried out at a German university hospital showed very instructive results: The waste with the lowest bacterial contamination was the waste from the operating theatre, followed by the waste from the isolation ward. The waste with the most colonies of bacteria and the most pathogenic microorganisms (Risk Group 2 and 3!) was the waste we produce at home – the household-waste!

This research tells us that there is absolute no reason to classify healthcare-waste as "dangerous" only because it comes from diagnosis or treatment of sick individuals. The fact, that waste contains "viable micro-organisms or theit toxins which are known or suspected to cause disease in animals or humans" is not sufficient to classify it as "infectious" (Code H6.2). Where are the evidence-based data to prove that infections have been transmitted to dustmen by healthcare-waste?

CP is pleased to recognize that the secretariat of the Sub-Committee of Experts on the Transport of Dangerous Goods cites the Priority Waste Stream Project of the European Community, of which definitions and recommendations are the results of very intensive discussions between experts on waste management and infectious disease specialists from different European countries.

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