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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-ninth session
Geneva, 3-12 (a.m.) July 2006
Item 7 of the provisional agenda

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

Comments on ST/SG/AC.10/C.3/56/Add 1
Changes to Chapter 2.6 of the Model Regulations

Submitted by the World Health Organization (WHO)

Background

1. At its twenty-eighth session held in December 2005, the Sub-Committee adopted changes to Chapter 2.6 regarding the requirements for transporting infectious substances. The consequences of these changes are brought to the attention of the Sub-Committee.
 - (a) 2.6.3.2.3.1 now reads, as a result of the adopted changes:

"Substances which contain pathogens but are nevertheless unlikely to cause disease in humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class".
 - (b) 2.6.3.2.3.6 *NOTE* the words "*and antibody detection in humans or animals*" have been deleted.

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2. WHO would like to express two concerns that result from these newly adopted changes.

Discussion

3. The substitution of the words "infectious substances" with "pathogens" in the context of 2.6.3.2.3.1 is not appropriate. In fact, an infectious substance is a substance that colonizes a host organism of a different species for the purpose of replication and production of "offspring". However, infections do not necessarily lead to disease. For example, a polio-immunized person may be reinfected several times with the polio virus, but not become symptomatic as a result of the body's ability to fight the infection, neutralize and destroy the intruder. A pathogen, however, by definition causes disease: from the Greek pathos = disease, and genesis = development; pathogen = agent that causes disease. It is a contradiction, therefore, to describe a pathogen as "unlikely to cause disease".
4. The adoption of the new text for 2.6.3.2.3.1 now creates a contradiction with section 2.6.3.2.3.6. Section 2.6.3.2.3.6 provides an exemption for human or animal specimens that have a minimal likelihood of containing infectious substances. Nevertheless, the Model Regulations recommend that these specimens be transported in a triple package and the package to be marked. The change to section 2.6.3.2.3.1 now allows substances that do contain pathogens to be completely exempt from any minimal packaging requirement if they are deemed unlikely to cause disease.
5. Antibodies are proteins used by the body's immune system to identify and neutralize foreign substances, including bacteria and viruses. Antibodies by themselves are not infectious, but are important markers of infections or other abnormal conditions in the host, such as autoimmune disease. In a situation where antibody detection is being considered for the identification of active infection, it is clear that the exemption should not apply. However, there may be situations in which antibody detection may be requested in the absence of any concern of infection (e.g. evaluation of vaccine induced immunity, diagnosis of autoimmune disease, etc.) for which the exemption would apply.

Proposals

6. Realizing that the adoption of the new text is contradictory and more importantly opens doors to the completely unregulated shipment of "pathogens" without any guidance as to the likelihood these pathogens present to cause disease, WHO urges the Sub-Committee to reevaluate the position adopted in December 2005, to consider returning to the text existing in the 14th Edition of the Model Regulations for section 2.6.3.2.3.1 and to reinstate section 2.6.3.2.3.2.
7. If the old version of 2.6.3.2.6.1. is considered inappropriate, it is suggested to delete 2.6.3.2.3.1 but leave 2.6.3.2.3.2, followed by the appropriate renumbering.
8. To clearly separate the situation where antibody detection is requested in absence of infection from any other situations, an alternative solution is proposed to the deletion adopted in December:

2.6.3.2.3.6: add the words "*and antibody detection in humans or animals in the absence of any concern for infection (e.g. evaluation of vaccine induced immunity, diagnosis of autoimmune disease, etc.)*."
