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

Infectious Substances

Transmitted by the expert from the United States of America

1. In document ST/SG/AC.10/C.3/2004/62 the expert from Canada has proposed certain amendments to the requirements for infectious substances. We have also considered the papers submitted by the World Health Organization (WHO) and the World Federation for Culture Collections (WFCC). In this paper the expert from the United States is proposing additional amendments that are intended to enhance the clarity and user friendliness of the UN Model Regulations.

**Proposals**

**Category A Definition and Indicative List**

2. The definition of Category A infectious substance in 2.6.3.2.2.1 should be amended to clarify that substances for ***which effective treatments are usually not available*** are considered to meet the definition of a Category A infectious substance and to clarify that a Category A infectious substance is one that would be fatal, life threatening or disabling to ***otherwise healthy individuals***.

3. Influenza virus is a good example to illustrate the need to amend the Category A definition. Although difficult to assess, annual influenza epidemics are thought to result in between three and five million cases of severe illness and between 250,000 and 500,000 deaths every year around the world. Most deaths currently associated with influenza in industrialized countries occur among the elderly over 65 years of age, and the chronically ill. Influenza poses a serious risk for infants, the elderly, and people suffering from medical conditions such as lung diseases, diabetes, cancer, kidney, or heart problems. The virus is easily passed from person to person through the air by droplets and small particles excreted when infected individuals cough or sneeze. Influenza spreads very readily through the general population. However, effective treatments are available and various types of influenza vaccines have been available and used for more than 60 years. Despite the availability of rapid diagnostic tests, the collection of clinical specimens for viral culture remains critical to provide information regarding circulating and emerging influenza subtypes and strains. This information is needed to guide decisions regarding influenza treatment and to formulate vaccine for the coming year.

4. Taking all of this into account, we would not consider the normal strains of influenza virus to be Category A infectious substances. The current Category A definition, however, does not provide a

sufficient level of detail to allow a person to make this determination. On this basis, the definition of a Category A substance should be amended as follows:

Category A: An infectious substance that is transported in a form that is capable of causing permanent disability, life-threatening or fatal ***disease in otherwise healthy*** humans or animals when exposure to it occurs ***and for which effective treatments and preventive measures are not available***. Indicative examples of substances that meet these criteria are given in the table in this paragraph.

5. In relation to the Category A indicative list Rabies should be removed as an example on the Category A list. Rabies should be transported as a Category B infectious substance. Hantaan virus should be qualified as Hantaviruses causing hemorrhagic fever with renal syndrome. We support the proposal from the World Organization for Animal Health (OIE) to amend the Category A indicative list to remove animal disease agents from the Category A indicative list, hence allowing them to be transported as Category B infectious substances.

**Definition of Cultures**

6. The expert from the United States agrees that further consideration is warranted with respect to whether all laboratory stock cultures should be assigned to Category A as mentioned in the WHO and WFCC papers. The expert from the United States agrees with the WHO and others that the definition of cultures and the current requirements that all cultured pathogens be assigned to Category A requires further consideration. We are in general agreement with the WHO proposal (INF.79) to amend the definition of "cultures" and to add a definition for "Patient Specimens". However, we believe that, as drafted, the proposed WHO definitions could still cause some confusion concerning the extent to which "patient specimens" are not included in the "cultures" definition. To clarify what we believe is WHO's intent in proposing the definitions, we suggest the following modification to the proposed WHO definition for "patient specimens":

***2.6.3.1.4 Patient specimens are cultures derived from human or animal materials that are collected directly from humans or animals, including but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, and body parts, and intended for diagnostic or clinical purposes. Examples of patient specimens include throat, stool or rectal swabs or other specimens that are intended for the diagnosis of suspected Category B infectious substance like Streptococcal pyogenes which causes Strep throat.***

The expert from the United States also supports the WHO proposal to amend section 2.6.3.2.2.2 to delete the words "except that cultures, as defined in 2.6.3.1.3, shall be assigned to UN 2814 or UN 2900 as appropriate." and to delete the words "or containing Category B infectious substances in cultures" in 2.6.3.5.1. We agree that the Category A list already identifies certain pathogens that are assigned to Category A only when in culture form (those where culture only is indicated) and that the revised Category A definition should be suitable for determining if other cultured substances that are not in the indicative list should be transported as Category A. The "cultures only" entries in the Category A indicative list should be maintained.

**P650 Pass/Fail criteria**

7. P650 paragraph (5) specifies a drop test but the pass/fail criteria are not clearly indicated. Additionally paragraph 6.3.2.2 should also be referenced since it provides information relative to how to prepare the package for the drop test. It is proposed that the criteria in 6.3.2.5 which states that "Following the appropriate drop sequence, there may be no leakage from the primary receptacle(s) which shall remain

protected by absorbent material in the secondary packaging be included in the text of paragraph (5) as follows:

***The completed package shall be capable of successfully passing the drop test in 6.3.2.5 as specified in 6.3.2.2 to 6.3.2.4 of these Regulations at a height of 1.2 m. Following the appropriate drop sequence, there shall be no leakage from the primary receptacle(s) which shall remain protected by absorbent material, when required, in the secondary packaging;***

**Comments on ST/SG/AC.10/C.3/2004/62:**

8. The expert from the United States supports proposal number 1 which includes an amendment to clarify the requirements for the transport of infected animals and Option 1 of proposal number 2 to delete SP 319. In relation to proposal 3 which changes the shipping name for UN3373, the expert from the United States supports consideration of an alternative shipping name to avoid unnecessary confusion. However, we would prefer the proper shipping name "**Biological specimen, Category B**".

9. In reference to the proposed amendment of 2.6.3.2.5(a) the wording "other than through statistical inference" is proposed. This wording could lead to even further confusion because people will want to question what is statistically acceptable.

10. The expert from the United States does not agree that substances where a low probability of infection exists and those that are unlikely to cause human or animal disease (previously Risk Group 1) should be subject to the UN Model Regulations. However, we recognize that there is never a 100% guarantee that healthy appearing individuals or animals will not harbour infectious pathogens even if they have no medical history or symptoms. We agree that healthy appearing individuals may still harbour infectious diseases (e.g. Human Immunodeficiency virus, Hepatitis B virus, Hepatitis C virus) and that it is not uncommon for individuals to unknowingly be infected with these viruses. However, we also acknowledge the daily exposure to pathogens within our normal environment (e.g. Germs from a person coughing or sneezing, foods infected with E-coli or Salmonella, water infected parasites such as Giardia or Schistosomiasis. Proper packaging is the main line of defence for reducing the potential exposure to transport workers. On this basis, the expert from the United States agrees that it would be useful to recommend that a minimal level of packaging be provided for certain biological specimens that are not subject to the Model Regulations. On this basis, we can agree to include a recommendatory note indicating that specimens of human or animal sources where a low probability exists that a dangerous pathogen is contained should be transported in appropriate packaging. The following amendments to 2.6.3.2.5 are proposed:

**2.6.3.2.5 The following substances are not subject to these Regulations unless they meet the criteria for inclusion in another class or division:**

**(a) substances that are transported for diagnostic purposes, other than to determine if an infectious pathogen is present and for which the medical history and symptoms of the patient do not provide reason to suspect that an infectious pathogen is present.**

***Note 1: Specimens such as excreta, secreta, blood and its components, tissue and tissue fluids, and body parts collected directly from healthy humans or animals that do not have a medical history or symptoms that would indicate the presence of pathogens subject to these Regulations and that are transported for purposes other than testing to determine if an infectious substance is present (routine blood counts, chemistry, cholesterol ,drug screening, glucose testing, urine or fecal testing, etc) are not subject to these Regulations but should be transported in packages that provide an appropriate level of protection from leakage to reduce the risks of exposure to those engaged in transport and handling of these specimens. The World Health Organization publication "Transport of Infectious Substances,***

***2004 (WHO/CDS/CSR/LYO/2004.9) provides guidance and information relevant to reducing the risks of infection to those engaged in the transport of infectious substances and recommends the use of appropriate packaging to prevent leakage and the risks to transport workers.***

***Note 2: Professional judgement is required to determine whether or not substances are exempt under this paragraph and should be based on the known medical history and symptoms of the source human or animal, endemic local conditions and the individual circumstances of the source human or animal (e.g., medical history).***

**(b) substances or materials where the concentration of pathogens is at a level naturally encountered and that have not been manipulated to enhance the viability of the pathogens.**

***Note: Examples of these substances include foodstuffs, water, soil or dust samples.***

**(c) substances which have been treated so that the pathogens have been inactivated and no longer pose a health risk; and**

**(d) dried blood spots, collected by applying a drop of blood onto absorbent material and** specimens for fecal ***occult*** blood screening tests.

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