# UN/SCETDG/25/INF.79

**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 World Health Organization (WHO)

**Background**

WHO has reviewed several papers referring to the transport of infectious substances, submitted to the UNSCETDG for consideration at the upcoming twenty-fifth session of 5-14 July 2004. Papers ST/SG/AC.10/C.3/2004/51 transmitted by the World Federation for Culture Collections (WFCC), ST/SG/AC.10/C.3/2004/52 transmitted by the World Organization for Animal Health (OIE), ST/SG/AC.10/C.3/2004/62 transmitted by Canada, ST/SG/AC.10/C.3/2004/61 transmitted by the Netherlands, ST/SG/AC.10/C.3/2004/73 transmitted by the International Civil Aviation Organization (ICAO), UN/SCETDG/25/INF.29 transmitted by WFCC, UN/SCETDG/25/INF.43 from the Joint Aviation Authorities (JAA) Dangerous Goods Study Group transmitted by the United Kingdom, and UN/SCETDG/25/INF.62 transmitted by the Secretariat, including other comments and suggestions were considered to provide the following recommendations.

**Proposals**

**1. Proposal to Exempt Certain Types of Diagnostic Specimens**

Some of the papers reviewed propose the regulatory exemption of substances ("diagnostic specimens") taken from healthy appearing individuals or specimens intended for non-infectious testing (routine blood counts, chemistry, cholesterol, glucose testing, urine or fecal testing, etc). WHO disagrees with the premise that these specimens should be exempt from infectious substance transport regulations due to a low probability of containing an infectious pathogen.

Healthy appearing individuals may still harbor infectious diseases (e.g. Human Immunodeficiency virus, Hepatitis B virus, Hepatitis C virus) and it is not uncommon for individuals to unknowingly be infected with these viruses. For these reasons WHO recommends “Standard Precautions” when handling and shipping human biological specimens. WHO is concerned that by exempting these specimens from the regulation, it would release them from all safety requirements, creating an unsafe situation of: (1) no minimal packaging standards; (2) no requirement for hazard communication; and (3) no requirement to report damaged

packages. WHO feels the lack of such standards will increase the likelihood of improper packaging which is likely to result in increase damaged packages and potential exposure to transport workers. WHO is also concerned that increased exposures will have a cascade effect and reduce the number of carriers that will transport infectious substances. Therefore, non-regulatory decisions may have adverse consequences on global public health.

## 2. Definition of Cultures

The current definition of cultures (2.6.3.1.3) appears to be a source of confusion. WHO recommends modification of the definition of culture to provide clarity. The revision includes the definition of the term "patient specimen" which incorporates text from special provision 319. The inclusion of the definition of "patient specimens" also helps to delineate that potentially infectious human and animal specimens are subject to this regulation, unless exempt under specific regulatory guidance.
Consequently, special provision 319 should be deleted.
(New text is shown in bold and underlined. Deleted text is shown with a strike-through line)

*2.6.3.1.3* *Cultures* ~~(laboratory stocks)~~ are the result of a process by which pathogens are **intentionally** ~~amplified or~~ propagated ~~in order to generate high concentrations, thereby increasing the risk of infection when exposure to them occurs. This definition refers to cultures prepared for the intentional generation of pathogens and does not include cultures intended for diagnostic and clinical purposes~~. **This definition does not include human or animal "patient specimens" as defined in 2.6.3.1.4.**

**2.6.3.1.4 *Patient Specimens* are human or animal materials, collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.**

Renumber 2.6.3.1.4 and 2.6.3.1.5 accordingly and delete special provision 319.

## 3. Transport of Cultures

Section 2.6.3.2.2.2 of the 13th edition of the Model Regulations mandates a packaging upgrade (from P650 to P620) for all Category B infectious substances that have been propagated to a concentrated culture form.

WHO is concerned that this policy is unwarranted given that these agents are less pathogenic, cause less severe infections and may be treatable. WHO points out that the chain-of-infection (as described in http://www.who.int/csr/resources/publications/WHO_CDS_ CSR_LYO_2004_9/en/) is composed of several factors: A. damage to package B. pathogen release C. exposure incident D. entry to host E. infectious dose F. host susceptibility G. available prophylaxis and treatment. Therefore, WHO suggests that the concentration of a Category B agent should not be the sole determinant to promote increased risk during transport. WHO feels the integrity of P650 packaging is adequate for the risk posed by these agents during transport.

WHO feels this upgrade policy downplays or negates the seriousness of the category A list.

Therefore, WHO requests modification of section 2.6.3.2.2.2 in the existing regulations, sighting that the Category A list already identifies the category B agents that require upgrade to P620 packaging when in culture form.

2.6.3.2.2.2 Category B: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B shall be assigned to UN 3373 ~~except that cultures, as defined in 2.6.3.1.3, shall be assigned to UN 2814 or UN 2900 as appropriate~~.

If the foregoing proposal is adopted, reference to cultures should be modified as follows:

2.6.3.5 Medical or clinical wastes

2.6.3.5.1 Medical or clinical wastes containing Category A infectious substances ~~or containing Category B infectious substances in cultures~~ shall be assigned to UN 2814 or UN 2900 as appropriate. Medical or clinical wastes containing infectious substances in Category B~~, other than in cultures,~~ shall be assigned to UN 3291.

## 4. Shipping name for Category B substances

WHO agrees that the adoption of the shipping name "DIAGNOSTIC SPECIMENS" or CLINICAL SPECIMENS" for UN 3373 will be a source of confusion, as the same terminology was used in conjunction with earlier versions of the Model Regulations that followed a different classification. WHO endorses the suggestion to change the shipping name for UN 3373 and proposes to change the shipping name for Category B substances to "**CATEGORY B BIOLOGICAL SUBSTANCES**".

## 5. Review of Category A List

WHO endorses the suggestions for changes to the list of Category A organisms transmitted by the World Organization for Animal Health (OIE) and encourages the regular review of this list.

## 6. Exemptions

The current exemptions appear to be a source of confusion. WHO proposes the following changes for clarification.

**2.6.3.2.3 Exemptions**

2.6.3.2.3**.1** Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.

2.6.3.2.**3.2** Substances **containing microorganisms that are non-pathogenic to humans or animals** are not subject to these Regulations unless they meet the criteria for inclusion in another class.

**2.6.3.2.3.3 Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk are not subject to these Regulations unless they meet the criteria for inclusion in another class.**

**2.6.3.2.3.4 Environmental samples (including food and water samples) that are not considered to pose a significant risk of infection are not subject to these Regulations unless they meet the criteria for inclusion in another class. Environmental samples suspected of containing Category-B substances in levels that pose a health risk shall be assigned to UN 3373. Environmental samples known or suspected of containing Category-A substances shall be assigned to UN 2814 or UN 2900 as appropriate.**

**2.6.3.2.3.5 Dried blood spots, collected by applying a drop of blood onto absorbent material, or faecal occult blood screening tests.**

2.6.3.2.~~4.~~**3.5** Blood or blood components which have been collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation are not subject to these Regulations.

The current section 2.6.3.2.5 is a major source of confusion and should therefore be deleted.

~~2.6.3.2.5 Substances for which there is a low probability that infectious substances are present, or where the concentration is at a level naturally encountered, are not subject to these Regulations. Examples are: foodstuffs, water samples, living persons and substances which have been treated so that the pathogens have been neutralized or deactivated.~~

WHO agrees with Canada's proposal to amend the current 2.6.3.2.6.

2.6.3.2.6~~.~~ **3.6 Unless an infectious substance cannot be consigned by any other means, live animals shall not be used to consign such a substance.** A live animal which has been intentionally infected and is known or suspected to contain an infectious substance shall only be transported under terms and conditions approved by the competent authority.

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