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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-sixth session  
Geneva, 29 November-7 December 2004  
Item 2 of the agenda

### TEXTS ADOPTED BY THE SUB-COMMITTEE AT ITS TWENTY-THIRD, TWENTY-FOURTH AND TWENTY-FIFTH SESSIONS AND RELATED PROPOSALS

#### ICAO's Intention to Issue an Addendum to the 2005-2006 ICAO TI

##### Transmitted by the expert from ICAO Secretariat

1. The purpose of this paper is to inform the Sub-Committee of Experts on the Transport of Dangerous Goods of the ICAO Dangerous Goods Panel's (DGP) intention to request approval from the Council of ICAO to issue an addendum to the 2005-2006 ICAO TI to take into account a number of amendments that were adopted at the 25<sup>th</sup> session of Sub-Committee. These amendments are being considered for incorporation in the 14<sup>th</sup> revised edition of the UN Model Regulations and will normally come into force from January 1, 2007. The DGP agreed with the recommendation by the UN Transport Secretariat that any text adopted by ICAO for implementation as from 1 January 2005 should be based on the UN recommendations to be adopted in December 2004 rather than on the Sub-Committee's decisions of July 2004. The request to the Council will be based on the amendments adopted by the Committee of Experts at its 2<sup>nd</sup> session on December 10, 2004. The amendments being considered for inclusion in the addendum pertain to the requirements for the transport of infectious substances and particularly are as follows:

to authorize the use of the new proper shipping name for category B infectious substances (Biological Substance, Category B);

to amend the indicative list of category A infectious substances;

to delete special provision SP 141 which is the same as SP 319 in the Model Regulations;

to include a note to inform users of the TI that the names "Diagnostic specimens" and "Clinical specimens" will be removed in the 2007-2008 TI and to include cross references in Dangerous Good List of the 2007/2008 edition of the TI for diagnostic and clinical specimens to refer users to the entry "Biological substance, Category B".

to amend the definition of cultures and add a definition for patient specimens;

to include the exceptions for dried blood spots and fecal occult blood screening tests should be included;

and

to include consequential amendments to the Category B sections where the reference to cultures has been deleted including paragraphs 2.6.3.2.2.2 and 2.6.3.5.1. The proposed amendments are also provided as an Annex to this information paper.

2. The DGP decided that it is necessary to adopt these amendments in the 2005-2006 ICAO TI because the use of the new proper shipping name and amendment of the definitions will reduce potential confusion in both the healthcare and aviation industries. Implementation delays may lead to non-acceptance of packages due to

confusion associated with the historical use of the term "diagnostic specimen". Confusion on whether the specimen is or is not infectious, may lead to rejection of packages containing patient specimens due to concerns about whether or not the shipment needs to meet the requirements of the Technical Instructions. Requiring all Category B cultures to be transported as Category A imposes an unnecessary burden on healthcare systems since Category B cultures pose a low risk in transport. This may have significant affects on patient care and public health. The amendments to the indicative list are necessary because the World Health Organization (WHO) and the World Organization for Animal Health (OIE) have identified substances on the list that do not meet the definition of Category A substances. The transport of the infectious substances as Category A substances when they do not meet the criteria for inclusion in Category A will result in unnecessarily greater costs to health care agencies.

3. Consistent with the recommendation from the UN Transport Secretariat the addendum will include a notification for consignors and freight forwarders that the inland transport regulations in some countries may not be consistent with the amendments adopted in the addendum. Annex 1 provides a more specific description of the amendments that will be included in the addendum and the rationale for making the changes in the 2005-2006 TI.

## **Annex 1 - Amendments that should be addressed in the addendum**

**(1) Revised proper shipping name for UN 3373 (Category B Infectious Substances).** The new proper shipping name "**Biological Substance, Category B**" will be added to the authorized shipping names "Diagnostic Specimen or Clinical Specimen" for Category B infectious substances in P650 and Table 3-1 of the Technical Instructions. The additional PSN will also be added to the Note in 2;6.3.1.2. It is intended that this name will replace the names "Diagnostic Specimen or Clinical Specimen" in the 2007-2008 TI so that there will only be one proper shipping name in the future. Providing an option now gives carriers and shippers a transition period. In addition a note indicating that the shipping names "Diagnostic Specimen or Clinical Specimen" will not be authorized from January 1, 2007. Since no other modes currently require that the proper shipping name be marked on the package currently that are no negative multimodal consequences associated with this amendment.

### **Item-1: Adverse Actions if not implemented in 2005:**

This change was adopted to reduce the confusion associated with the old definition of "diagnostic specimens" which in some instances was considered to be non-infectious and therefore not regulated. The proper shipping name is required to be marked adjacent to the UN 3373 diamond marking (i.e. serves as hazard communication) on packages and must be indicated on a written document (such as an air waybill) or on the package. Implementation delays may lead to non-acceptance of packages due to confusion associated with the historical use of the term "diagnostic specimen". Confusion as to whether the specimen is or is not infectious, may lead to rejection of shipments due to concerns about appropriate packaging and with respect to operators that are designated or not designated to transport dangerous goods and whether they carry these infectious substances. This could have serious affects on patient care and public healthcare systems.

**(2) The indicative list of Category A substances in 2;6.3.2.2.1 will be amended.** WHO and OIE recommended several changes to the Category A list.

### **Item-2: Adverse Actions if not implemented in 2005:**

Implementation delays are likely to have adverse consequences on long standing domestic and international disease surveillance programs due to the increase cost associated with having to declare and ship routine surveillance specimens in P620 packaging. This also improperly promotes the idea that these specimens pose a significant public health risk as defined by the definition for Category-A infectious substances. Once ingrained, attempting to change this public perception, may prove difficult at a later date. Increased public fears may also lead to non-acceptance of shipments, which could have significant affects on patient care and public health improvement efforts.

A person classifying infectious substances uses the Indicative List as a quick reference to determine whether or not an Infectious Substance would be considered a 'Category A' substance. However, with respect to the proposed additions to the list, that person is obligated to classify any infectious substance as Category A if, when exposure to it occurs, it is capable of causing permanent disability, life-threatening or fatal disease to humans or animals. Therefore the additions should be classified as Category A whether or not they're on the list. For those substances removed from the list the worst that can happen is that they will still be classified as Category A Infectious Substances and will be transported in compliance with the more stringent provisions of for UN2814 and 2900 infectious substances provisions until the revised list is published.

Since the list is indicative no negative multimodal consequences associated with this amendment are anticipated.

**(3) Revise the definition of cultures and add a definition for patient specimens in 2;6.3.1.3, and amend the definition of Category B infectious substances in 2;6.3.2.2.2 and the text in 2.6.3.5.1.**

**Item-3: Adverse Actions if not implemented in 2005:**

Implementation delays are likely to have adverse consequences on patient care and long standing disease surveillance programs, due to the increase cost associated with having to declare and ship a less hazardous Category-B infectious substance in P620 packaging. This improperly promotes the idea that these specimens pose a significant public health risk as defined by the definition for Category-A infectious substances. Once ingrained, attempting to change this public perception may prove difficult at a later date. Increased public fears may also lead to non-acceptance of packages, which will have devastating affect on patient care and public health prevention efforts. The new definitions provide clarification and resolve confusion associated with the term "Culture" when used by the research community vs. the medical community. Requiring Category B cultures to be transported as Category A imposes an unnecessary burden on healthcare systems since Category B cultures pose a low risk in transport just as these substances pose a low risk in transport when they are transported in a form other than a culture. Immediate implementation of this amendment will assist the shipper in making appropriate packaging decisions and enhance regulatory compliance. While this may impose some multimodal problems it is anticipated that multilateral approvals could be developed to address the difference in the two year time frame.

**(4) Amend the definition of Category A infectious substances in 2;6.3.2.2.1**

The definition is a critical factor that is used to determine the appropriate classification of infectious substances. The amendment provides clarification with respect to the substances that are assigned to category A and Category B. The words "in otherwise healthy" were added after "fatal disease" and the word "to" was deleted before "humans" so that the text now reads "...life threatening or fatal disease in otherwise healthy humans or animals."

**Item-4: Adverse Actions if not implemented in 2005:** This amendment will clarify what is intended to be transported as a Category A infectious substance. It will prevent unnecessary confusion and should be implemented as soon as possible. No multimodal difficulties are anticipated as a result of this amendment.

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