# UNSCETDG/18/INF.18

**COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS**
**Sub-Committee of Experts on the Transport of Dangerous Goods**
**(Eighteenth session, Geneva, 3-14 July 2000, agenda item 5 (e))**

## MISCELLANEOUS DRAFT AMENDMENTS TO THE MODEL REGULATIONS ON THE TRANSPORT OF DANGEROUS GOODS

## Infectious substances

## Classification and packaging of diagnostic specimens

## Transmitted by the Hazardous Materials Advisory Council (HMAC)

### Background

1. At the seventeenth session of the Sub-Committee of Experts the subject of the classification and packaging of diagnostic specimens was addressed in a joint paper, ST/SG/AC.10/C.3/1999/83, produced by the experts of Germany and the United Kingdom. During discussions at that session, the principles advanced in that paper were agreed by the Sub-Committee. However the experts of Germany and the United Kingdom agreed to produce a revised proposal to reflect the suggestions and concerns of other experts. It is that revised proposal in document ST/SG/AC.10/C.3/2000/15, which HMAC wishes to comment on in this Information Paper.

2. HMAC agrees with the experts from the United Kingdom and Germany that consignors, medical practitioners and laboratory personnel, who are often not otherwise involved in the transport of dangerous goods, face difficulties in determining the classification of diagnostic specimens and meeting packaging requirements.

3. In general, HMAC supports the proposal in -/2000/15 that an appropriate definition and packaging requirements for diagnostic specimens should, so far as possible:

- avoid direct reference to WHO Risk Groups, which had been developed for purposes other than transport;
- avoid reference to pathogens most of which will be low hazard and low infectivity and which are present in almost all diagnostic specimens;
- limit, so far as practicable, the need for professional judgements to be made on the presence or otherwise of infectious substances;
- limit the application of requirements in transport to those commensurate with the real, rather than the perceived, risk;
- require easily obtainable, inexpensive packaging appropriate to the degree of hazard and conditions of transport;
- permit ready and enforceable consignment.

**Specific comments on proposal**

4. HMAC supports the proposal to modify existing 2.6.3.1.3, however, would suggest some additional text to add clarity to the second sentence (see bolded text) as follows:

> "*2.6.3.1.3 Diagnostic specimens* are any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids being transported for diagnostic or investigation purposes, but excluding live infected animals.
>
> Diagnostic specimens shall be assigned to UN xxxx unless the source patient or animal has or may have a serious human or animal disease which can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatment and preventative measures are not usually available, in which case they shall be assigned to UN 2814 or UN 2900 **and identified as *'Infectious substance, affecting …'***.
>
> ***Note:*** *1. Blood which has been collected for the purpose of blood transfusion or for the preparation of blood products, and blood products and any tissues or organs intended for use in transplants are not regarded as dangerous goods for transport.*
>
> *2. Assignment to UN 2814 or UN 2900 would be based on known medical history of the patient/animal, endemic local conditions, symptoms of the patient/animal or professional judgement concerning individual circumstances of the patient/animal."*

5. HMAC supports the proposal to insert a new Packing Instruction in 4.1.4, however, suggests the following modifications.

- removal of seemingly unnecessary text with "General Provisions (i)" and
- increase the primary receptacle and outer packaging limitations for liquids to the quantities currently acceptable within the ICAO Technical Instructions.

The revised proposal to read as follows:

| **P 650** | **PACKING INSTRUCTION** | **P 650** |
|---|---|---|

This instruction applies to UN XXXX

General Provisions

(i) Diagnostic specimens shall be packed in good quality packagings, which shall be strong enough to withstand the shocks and loadings normally encountered during transport. Packagings, when prepared for shipment, shall be constructed and closed so as to prevent any loss of which might be caused under normal conditions of transport, by vibration, or by changes in temperature, humidity or pressure.

(ii) Primary receptacles shall be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packagings shall be secured in outer packagings with suitable cushioning material. Any leakage of the contents shall not substantially impair the protective properties of the cushioning material or of the outer packaging.

(iii) For carriage each package shall be clearly and durably marked with the words DIAGNOSTIC SPECIMENS

(iv) Outer packagings may consist of [paper], [fibreboard], plastics or metal.

<u>For Liquids</u>

(i) The primary receptacle(s) shall be leakproof and not contain more than 500ml.

(ii) There shall be absorbent material placed between the primary receptacle and the secondary packaging; if several fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated so as to prevent contact between them. The absorbent material, such as cotton wool, shall be in sufficient quantity to absorb the entire contents of the primary receptacles; and there must be a secondary packaging which must be leakproof.

(iii) The primary receptacle or the secondary packaging shall be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar).

(iv) The outer packaging shall not contain more than 4L.

<u>For Solids</u>

(i) The primary receptacle(s) shall be siftproof and not contain more than 100g.

(ii) If several fragile primary receptacles are placed in a single secondary packaging , they shall be either individually wrapped or separated so as to prevent contact between them and there must be a secondary packaging which must be waterproof

(iii) The outer packaging shall not contain more than 500g

Providing that diagnostic specimens are packed in accordance with this Packing Instruction, no other requirements of these Model regulations shall apply.

**Consequential amendments**

6. HMAC believes the following consequential amendments would need to be considered in addition to those identified by the experts from Germany and the United Kingdom in paper -/2000/15, in order to completely address the amendments put forward in the proposal.

7. 2.6.3.1.2 Modify the existing definition of "biological products" to remove reference to pathogens and risk groups as follows:

- Delete the existing sentence "For the purposes of these Regulations, biological products are divided into the following groups:";
- 2.6.3.1.2 (a) Delete existing text;

- 2.6.3.1.2 (b) Insert existing text as a second paragraph in 2.6.3.1.2 as follows:

"Biological products manufactured and packaged in accordance with the requirements of national governmental health authorities and transported for the purposes of final packaging or distribution, and use for personal health care by medical professionals or individuals are not subject to the regulations applicable to Division 6.2."

- 2.6.3.1.2 (c) Delete existing text;
- Retain the existing "*Note*" following 2.6.3.1.2

8. 2.6.3.2.1 Revise or delete existing text to remove reference to WHO risk groups.

9. 2.6.3.2.2 Delete existing text to remove the criteria for each risk group and the subsequent "*Note*". If the Sub-Committee determines that 2.6.3.2.1 can be deleted, then the section 2.6.3.2 is deleted entirely.

10. 2.6.3.3.1 Delete existing text as it is now unnecessary.

11. 2.6.3.3 In the title, delete "Biological products".

12. 2.6.3.3.3 This text relative to "Waste clinical or (bio)medical substances…" could be moved to 2.6.3.1.5 and 2.6.3.3.3 and the title text in 2.6.3.3, therefore deleted.

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