UNITED NATIONS **ST**

Secretariat

Distr.
GENERAL

ST/SG/AC.10/C.3/1999/83
22 September 1999

Original: ENGLISH

COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS
Sub-Committee of Experts on the Transport of Dangerous Goods
(Seventeenth session, Geneva, 6-17 December l999, agenda item 5 (f))

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

Infectious substances

Classification and packaging of diagnostic specimens

Transmitted by the experts from Germany and the United Kingdom

Background

1. At the sixteenth session of the Sub-Committee of Experts the subject of the classification and packaging of diagnostic specimens was addressed in papers ST/SG/AC.10/1998/47, 1998/48 and Information Paper 28 from the expert from Germany and Information Paper 24 from the expert from the United Kingdom. It was agreed that the difficulties that consignors, medical practitioners and laboratories, who are often not otherwise involved in the transport of dangerous goods, face in determining the classification of diagnostic specimens and meeting packaging requirements do not sit readily with the procedures of health services. Particular problems arise with the consignment of diagnostic specimens through the postal system.

2. Several experts agreed that this problem needed to be addressed and some said that they favoured the approach suggested by the United Kingdom in Information Paper 24. However, as most delegations had not had time to study the papers in detail, it was agreed that the experts from Germany and the United Kingdom, in consultation with the experts from the World Health Organisation (WHO), should cooperate in submitting a new proposal for the 17th Session.

3. Experts from Germany, United Kingdom and WHO met in London on 3 September to consider the issue, taking account of other views expressed, notably written comments received from HMAC. It was agreed by all participants 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 consignment using postal services, enforceable both by the competent authority and the postal services themselves.

4. On the basis of this approach, consensus was reached on an appropriate definition and packaging requirements.

Proposal on classification

5. It is proposed that diagnostic specimens be assigned a separate UN number and that guidance be offered in the form of a Note for the basis on which assignment of diagnostic specimens as infectious substances should be made.

6. Add a new UN number DIAGNOSTIC SPECIMENS as follows:

1	2	3	4	5	6	7	8	9	10	11
XXXX	DIAGNOSTIC SPECIMENS	6.2	-	-	-	NONE	P650	-	-	-

7. Delete existing 2.6.3.1.3, insert new 2.6.3.1.3 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.

Note: *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."*

8. Insert new Packing Instruction in 4.1.4 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, including trans-shipment between transport units and/or warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings shall be constructed and closed so as to prevent any loss of contents when prepared for transport 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 SPECIMEN in the language of the consignor. Documentation is not required.

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

<u>For Liquids</u>

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

(ii) There shall be absorbent material placed between the primary receptacle and the secondary packaging; if several primary receptacles are placed in a single secondary packaging, they shall be individually wrapped 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 500ml.

<u>For Solids</u>

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

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

(iii) The outer packaging shall not contain more than [200g].

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