

**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-second session, 2-6 December 2002,
agenda item 3)**

**TEXTS ADOPTED BY THE SUB-COMMITTEE AT ITS NINETEENTH, TWENTIETH AND
TWENTY-FIRST SESSIONS**

Comments on the Proposed Text for Infectious Substances (P650)

Transmitted by the expert from the United States of America


Background

1. In ST/SG/AC.10/C.3/2002/76 the expert from the United States proposed amendments to the requirements in the new P650 (see ST/SG/AC.10/C.3/42/Add.3). After further consideration and discussions with members of the affected industry, we believe that further amendments to P650 are necessary. We have received a number of comments from industry representatives expressing concern about confusion that may result from the differences between the requirements for Part 1 and Part 2 packagings for specimens in packing instruction P650. There are some requirements for the larger packagings that are less protective than those for the smaller packagings. The current limits do not take into account the need to exclude the mass of refrigeration materials such as ice, dry ice or liquid nitrogen from the maximum quantities per outer packaging. We believe that the requirement to subject and mark the larger Part 2 packagings to the requirements of Chapter 6.1 will over complicate the regulations. Specifically, we are proposing:
 - to include a requirement that manufacturers and subsequent distributors provide closure instructions and that consignors ensure that closure instructions are followed;
 - that the requirements for the larger packagings specified in Part 2 be merged into Part 1 and to remove the quantity limits in Part 1; and
 - to include a requirement that consignors receive instructions in accordance with the requirements in P650.

These amendments are proposed to simplify the requirements consistent with the objective of implementing a stand alone packing instruction that can be used by consignors (e.g., medical professionals, home care practitioners) to meet the requirements of the Model Regulations.

Proposal

2. Replace the proposed P650 with the following:

P650	PACKING INSTRUCTION	P650
This packing instruction applies to UN 3373		
<p>(1) The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including transshipment between transport units and between transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings shall be constructed and closed to prevent any loss of contents that might be caused under normal conditions of transport by vibration or by changes in temperature, humidity or pressure. Consignors and persons who prepare packagings for transport shall ensure that packagings are prepared and closed in accordance with the information provided by the manufacturer.</p> <p>(2) The packaging shall consist of three components:</p> <ul style="list-style-type: none"> (a) a primary receptacle, (b) a secondary packaging, and (c) an outer packaging. <p>(3) Primary receptacles shall be packed in secondary packagings 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 compromise the integrity of the cushioning material or of the outer packaging.</p> <p>(4) For transport, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The width of the line shall be at least 2 mm; the letters and numbers shall be at least 6 mm high.</p> <div style="text-align: center; margin: 20px 0;">  </div> <p>(5) The completed package shall be capable of successfully passing the drop test in 6.3.2.5 as specified in 6.3.2.3 and 6.3.2.4 <i>of the Model Regulations</i> except that the height of the drop shall not be less than 1.2 m. The smallest external dimension of outer packagings shall be not less than 100 mm. <i>Packaging manufacturers and subsequent distributors shall provide information regarding closure procedures.</i></p>		

P650	PACKING INSTRUCTION	P650
(6)	For liquid substances: (a) The primary receptacle(s) shall be leakproof and shall not contain more than 500 mL of the liquid substance. (b) The secondary packaging shall be leakproof. (c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them. (d) Absorbent material shall be placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging. (e) The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar). (f) The outer packaging shall not contain more than 4 litres of the liquid substance.	
(7)	For solid substances: (a) The primary receptacle(s) shall be sift proof and shall not contain more than 500 g of the solid substance. (b) The secondary packaging shall be siftproof. (c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them. (d) The outer packaging shall not contain more than 4 kg of the solid substance.	
(8)	Refrigerated or frozen specimens: Ice, Dry ice and liquid nitrogen (a) When dry ice or liquid nitrogen is used to keep specimens cold and packed in accordance with Part 1 or 2, all applicable requirements of these Regulations shall be met. When used, ice or dry ice shall be placed outside the secondary packagings or in the outside packaging or an overpack. Interior supports shall be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack shall be leakproof. If Carbon dioxide, solid (dry ice) is used, the packaging must be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings and shall be marked " Carbon dioxide, solid " or " Dry ice ". (b) The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures that could result if refrigeration were lost.	

P650	PACKING INSTRUCTION	P650
(9)	<p>Infectious substances in Category B, <i>except cultures (see definition in 2.6.3.1.3) that</i> are packed and marked in accordance with this packing instruction are not subject to any other requirement in these Regulations. <i>Consignors shall receive instructions in complying with the requirements of this packing instruction. The instructions shall include information relative to the classification of infectious substances so that the consignor can determine that the substances offered for transport are acceptable and appropriate for transport according to this packing instruction. The instructions shall also include guidance on the preparation, assembly and closing of the packaging. When a patient is required to return samples to a doctor's office, a hospital or a laboratory for analysis, the patient shall be provided with clear instructions on filling and closing these packages to ensure that the package is correctly prepared for transport.</i></p>	
