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-fourth session
Geneva, 3-10 December 2003
Item 9 of the provisional agenda

Infectious substances

Transmitted by the International Civil Aviation Organization (ICAO)

Introduction

The ICAO Dangerous Goods Panel (DGP) held its 19th meeting in Montreal from 27 October to 7 November 2003. The primary purpose of the meeting was to finalize the content of the 2005-2006 edition of the ICAO Technical Instructions.

During the meeting the panel considered the requirements for transporting Division 6.2, Infectious Substances, in the 13th Edition of the UN Model Regulations; discussion focused on packing instruction P650.

The panel agreed to a number of revisions to P650 and that revised document is attached for the Sub-Committee. The changes are underlined and written in bold print. It should be noted that the panel felt that these revisions were required for safety reasons.

Revisions to P650 as agreed by the ICAO DGP

1. In section (2) of P650, the panel agreed to amend paragraph (c) to require a rigid outer packaging. The panel agreed that such packaging would provide additional protection for primary receptacles from crushing or puncturing during transport. It was noted that rigid outer packaging was already in common use and that the majority of incidents that had occurred had been with non-rigid packaging.

2. In section (4) of P650, the panel agreed to specify that the mark be displayed in a diamond-shape and that each side must have a length of at least 50 mm. The panel felt that the size of the mark, consistent with the smallest dimension allowed for the Division 6.2 label for Category A substances, was needed to be specified to ensure visibility.

The panel further agreed that the shipping name "Diagnostic specimen" or "Clinical specimen" must be displayed on the package adjacent to the diamond-shaped mark. The panel felt that since a transport document is not required for UN3373, the shipping name on the package would provide additional useful information, noting that the diamond-shaped mark would otherwise be the only means of hazard communication.

3. The panel agreed to add a new section – (5) – to require that at least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm. The panel felt that a minimum package size is necessary to ensure safe handling in sorting facilities and to prevent damage during handling.

4. In the section re-numbered (7) pertaining to liquid substances, the panel agreed, in paragraph (a), to a quantity limit for primary receptacles of 1 litre and agreed to add a new paragraph (f) to add a quantity limit for the outer package of 4 litres. The quantity for the outer package excludes ice, dry ice or liquid nitrogen when these are used to keep specimens cold. The panel felt that quantity limits in the 2003-2004 edition of the Technical Instructions in special provision A81 and in P650 should be maintained

5. In the section re-numbered (8) pertaining to solid substances, the panel agreed, in paragraph (a), to add a direction that the quantity in the primary receptacle must not exceed the outer packaging mass limit. It was noted that no specific inner packaging limit was required since solid substances were much less likely to escape from the packagings. The panel also agreed to add a new paragraph (d) limiting the quantity in an outer package to 4 kg. This quantity does not include packages containing body parts, organs or whole bodies and, in addition, excludes ice, dry ice or liquid nitrogen when these are used to keep specimens cold. The panel felt that these quantity limits are necessary to ensure safe transport by air.

The panel agreed to add a new paragraph (e) to provide direction for solids where liquids are absorbed and where there is any doubt that residual liquid may be present during transport.

6. In the section re-numbered (9), the panel agreed to delete the requirement for marking dry ice since this requirement is handled elsewhere in the Technical Instructions but noted the text relating to the design and construction of packagings to prevent a dangerous release of carbon dioxide was valuable and should be retained.

7. The panel agreed to add a new section (10) and to re-number the existing section (10) as section (12). The new section (10) requires that overpacks be marked when a packages are in an overpack and the marking on them cannot be seen.

8. In the section re-numbered (11), the panel agreed to add five new subsections

- to require an alternate document or marking on the package of the proper shipping name, the UN number and the name, address and telephone number of a responsible person,
- to require classification of infectious substances to be done in accordance with the appropriate section of the Technical Instructions,
- to require incident reporting,
- to require inspection for damage or leakage, and
- to prohibit Category B infectious substances from being transported by passengers or crew in carry-on or checked luggage or on their person.

The panel felt that these requirements were required to ensure the safe transport of Category B substances by air.

9. It was noted that packages containing infectious substances sometimes contained small quantities of other dangerous goods, used to stabilize or prevent the degradation of the specimen. The panel agreed to add a new section (13) to provide guidance to shippers and carriers when such other dangerous goods are packed in the same primary receptacle containing Category B infectious substances.

Additional points of interest

10. The panel noted no information is given concerning an acceptable means of packaging bodies or body parts; the Sub-Committee is requested to consider this matter.

11. The panel noted the a problem relating to substances falling under Category B with the proper shipping name “Diagnostic specimen”; many substances which might reasonably be called diagnostic specimens in the normal usage of these words would not in fact be dangerous goods of Division 6.2 and would therefore be not subject to the provisions of the Technical Instructions. It was noted the new classification provisions contained in paragraph 2.6.3.2.5 listed several substances which would not be included in Category B, which was helpful, but that most of substances should not be considered as dangerous goods in the first place. The Sub-Committee is requested to provide clarification, especially regarding the exceptions contained in 2.6.3.2.5.

12. The Sub-Committee is requested to consider adding a further exception to cover dry blood spots. These are blood specimens drawn from healthy patients (typically infants) for routine test and screening purposes. The blood is allowed to saturate paper and then dry completely. The specimens pose an extremely minimal risk of infection and it is considered that they do not need to meet the requirements of Division 6.2.

P650	Packing Instruction	P650

This packing instruction applies to UN 3373

(1) The packaging must be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including transhipment 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 must be constructed and closed to prevent any loss of content that might be caused under normal conditions of transport by vibration or by changes in temperature, humidity or pressure.

(2) The packaging must consist of three components:

(a) a primary receptacle,

(b) a secondary packaging, and

(c) **a rigid** outer packaging.

(3) Primary receptacles must 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 must be secured in outer packagings with suitable cushioning material. Any leakage of the contents must not compromise the integrity of the cushioning material or of the outer packaging.

(4) For transport, the mark illustrated below must be displayed on the external surface of the outer packaging on a background of a contrasting colour and must be clearly visible and legible. **The mark must be in the form of a square set at an angle of 45º (diamond-shaped) with each side have a length of at least 50 mm, t**he width of the line shall be at least 2 mm **and** the letters and numbers shall be at least 6 mm high. **The proper shipping name "Diagnostic specimen" or "Clinical specimen" in letters at least 6mm high must be marked on the outer package adjacent to the diamond-shaped mark.**

(5) At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100mm.

(6) The completed package must be capable of successfully passing the drop test in 6;6.2. as specified in 6;6.1.5 of the Instructions except that the height of the drop must not be less than 1.2m.

P650	Packing Instruction	P650

(7) For liquid substances

(a) The primary receptacle(s) must be leakproof **and must not contain more than 1 litre.**

(b) The secondary packaging must be leakproof.

(c) Ìf multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

(d) Absorbent material must be placed between the primary receptacle(s) and the secondary packaging. The absorbent material must be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substances will not compromise the integrity of the cushioning material or of the outer packaging.

(e) The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar).

(f) **The outer package must not contain more than 4 litres. This quantity excludes ice, dry ice, or liquid nitrogen when used to keep specimens cold.**

(8) For solid substances:

(a) The primary receptacle(s) must be siftproof **and must not exceed the outer packaging mass limit**.

(b) The secondary packaging must be siftproof.

(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

(d) **Except for packages containing body parts, organs or whole bodies, the outer package must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.**

(e) **If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then a packaging suitable for liquids, including absorbent materials, must be used.**

(9) Refrigerated or frozen specimens: Ice, Dry ice and liquid nitrogen

(a) When dry ice or liquid nitrogen is used to keep specimens cold, 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 shall 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 shall 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

(10) **When packages are placed in an overpack, the package markings required by this packing instruction must either be clearly visible or be reproduced on the outside of the overpack.**

(11) Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement in these Instructions **except for the following**:

(i) **the proper shipping name, UN number and the name, address and telephone number of a responsible person must be provided on a written document (such as an air waybill) or on the package;**

(ii) **classification must be done in accordance with 2;6.3.2;**

(iii) **the incident reporting requirements in 7;4.4 must be met;**

(iv) **the inspection for damage or leakage requirements in 7;3.1.3 an d 7;3.1.4; and**

(v) **passengers and crew members are prohibited from transporting infectious substances either as or in carry-on baggage or checked baggage or on their person**.

(12) Clear instructions on filling and closing such packages must be provided by packaging manufacturers and subsequent distributors to the consignor or to the person who prepares the package (e.g. patient) to enable the package to be correctly prepared for transport.

(13) **Other dangerous goods must not be packed in the same packaging as Division 6.2 Infectious Substances unless they are necessary for maintaining the viability, stablizing or preventing degradation or neutralizing the hazards of the infectious substances A quantity of 30 ml or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction no other requirements in these Instructions need be met.**
