Introduction

1. The Sub-Committee may recall that in the context of discussions on paper ST/SG/AC.10/C.3/2004/67 on the editorial revisions of the UN design type packaging tests submitted by the expert from the Netherlands, it was noted that Chapter 6.3 was significantly out of line with more recently developed text. The expert from the United Kingdom believes that Chapter 6.3 which deals with the packaging of infectious substances needs to be made clearer. Below are draft proposals on the reformatting of this chapter. The United Kingdom is aware that more work is needed on this paper before it can be submitted as a formal document. However the expert of the United Kingdom suggests that the Sub-Committee regard this Information paper as a thought starter paper and hopes there will be time for brief discussion during the December session. If the Sub-Committee are in agreement that changes are needed then the expert from the United Kingdom would hope to produce a formal paper for July 2005.

2. The current Chapter 6.3 is not aligned to any other packaging chapter; the text is inadequate, ambiguous and conflicts with Packing Instruction 620. This paper attempts to align Chapter 6.3 more closely to the other packaging chapters without changing the test requirements.

3. As an example of the problems, there is a difference in terminology between the term “intermediate packaging” used in 6.3 whereas “secondary packaging” is used in P620. The latter has been inserted in this document but this will need to be looked at in relation to Class 1 packing instructions which use the term intermediate packaging in a slightly different context.

4. Various explanations, comments and questions are shown in italics on which the expert from the United Kingdom would particularly welcome the views of others.

6.3.1 General

6.3.1.1 This chapter applies to packagings for infectious substances and does not apply to:

packagings whose net mass exceeds 400Kg
packagings with a capacity exceeding 400litre
packagings for whole organs
packagings whose components include a liquid nitrogen cooling system
[check gases]
[packaging for diagnostic specimens] note consequential amendment to P650 (5) in final paper
6.3.1.2 Packagings used for infectious substances will comprise:

(a) an outer packaging of a type defined in 6.1.4.

(b) a secondary packaging (definition/specification?) which shall be watertight and may [must] be capable of withstanding an internal pressure differential of 95 kPa.

(c) one or more primary receptacles (examples?)

6.3.1.3 Packagings shall be manufactured, and tested under a quality assurance programme which satisfies the competent authority in order that each packaging meets the requirements of the Chapter.

6.1.1.5 Manufacturers and subsequent distributors of packagings shall provide information regarding procedures to be followed and a description of the types and dimensions of closures (including required gaskets) and any other components needed to ensure that packages as presented for transport are capable of passing the applicable performance tests of this Chapter.

6.3.2 Code for designating types of packagings

6.3.2.1 The codes for types of packaging are set out in 6.1.2.7.

6.3.2.2 The letters “U” or “W” may follow the packaging code. The letter “U” signifies a special packaging conforming to the requirements of 6.3.5.1.8 The letter “W” signifies that the packaging, although, of the same type indicated by the code is manufactured to a specification different from that in 6.1.4 and is considered equivalent under the requirements 6.3.1.2.

6.3.3 Marking

NOTE 1: The marking indicates that the packaging which bears it corresponds to a successfully tested design type and that it complies with the requirements of the Chapter which are related to the manufacture, but not to the use, of the packaging

NOTE 2: The marking is intended to be of assistance to packaging manufacturers, reconditioners, packaging users, carriers and regulatory authorities. In relation to the use of a new packaging, the original marking is a means for its manufacturer(s) to identify the type and to indicate those performance test regulations that have been met.

6.3.3.1 Each packaging intended for use according to these Regulations shall bear markings which are durable, legible and placed in location and of such a size relative to the packaging as to be readily visible. For packagings with a gross mass of more than 30 kg, the markings or a duplicate thereof shall appear on the top of or on a side of the packaging. Letters, numerals and symbols shall be at least 12 mm high, except for packagings of 30 litres or 30 kg capacity or less, when they shall be at
least 6 mm in height and for packagings of 5 litres or 5 kg or less when they shall be of an appropriate size.

(This takes the text from Chapter 6.1)

A Packaging that meets the requirements of this section and of 6.3.2 shall be marked with:

(a) The United Nations packaging symbol;
(b) The code designating the type of packaging according to the requirements of 6.1.2;
(c) The text “Class 6.2”;
(d) The last two digits of the year of manufacture of the packaging.
(e) The state authorizing the allocation of the mark, indicated by the distinguishing sign for motor vehicles in international traffic;
(f) The name of the manufacturer or other identification of the packaging specified by the competent authority.

(old (g) is now 6.3.2.2)

Each element of the marking applied in accordance with (a) to (g) shall be clearly separated, e.g. by a slash or space, so as to be easily identifiable.

6.3.1.2 Example of marking:

4G/CLASS 6.2/01 as in 6.3.1.1 (a), (b), (c) and (d)
S/SP-9989-ERIKSSON as in 6.3.1.1.(e),(f)

6.3.4 Requirements for Packagings

6.3.4.1 The provisions of 6.1.4 apply to packagings for this Chapter.

6.3.4.2 [Secondary Packaging definition/specification?]

A secondary packaging shall be watertight and may be capable of withstanding an internal pressure differential of 95 kPa

(It is suggested a general description of a secondary be incorporated)

(Instead of watertight should the word be leaktight?)

6.3.5 Test Requirements for Packagings

6.3.5.1 Performance and frequency of tests

6.3.5.1.1 Other than for packagings for live animals (see 2.6.3.6), [and] whole organs [and organisms]

(The term organism is not used in P620 and may be unnecessary)

(from 6.3.2.1)
6.3.5.1.2 The design type of each packaging shall be tested as provided in 6.3.5 in accordance with procedures established by the competent authority.

(from 6.1.5.1.1)

6.3.5.1.3 Tests shall be successfully performed on each packaging design type before such packaging is used. A packaging design type is defined by the design, size, material and thickness, manner of construction and packing, but may include various surface treatments. It also includes packagings which differ from the design type only in their lesser design height. Add "no package shall be less than 100mm in any dimension."

(from 6.1.5.1.2)

6.3.5.1.4 Tests shall be repeated on production samples at intervals established by the competent authority.

(from 6.1.5.1.3 except second sentence not applicable to 6.2 packagings)

6.3.5.1.5 Tests shall also be repeated after each modification which alters the design, material or manner of construction of a packaging.

(from 6.1.5.1.4)

6.3.5.1.6 The competent authority may permit the selective testing of packagings that differ only in minor respects from a tested type, e.g. smaller sizes of inner packagings or inner packagings of lower net mass; and packagings such as drums, bags and boxes which are produced with small reductions in external dimension(s) [modify for secondary]

(from 6.1.5.1.5)

6.3.5.1.7 Provided an equivalent level of performance is maintained, the following variations in the primary receptacles place within a secondary packaging are allowed without further testing of the completed package:

(a) Primary receptacles of equivalent or smaller size as compared to the tested primary receptacles may be used provided:

(i) The primary receptacles are of similar design to the test primary receptacle (e.g. shape: round, rectangular, etc);

(ii) The material of construction of the primary receptacle (glass, plastics, metal etc.) offers resistance to impact and stacking forces equal to or greater than that of the originally tested primary receptacle;

(iii) The primary receptacles have the same or smaller openings and the closure is of similar design (e.g. screw cap, friction lid, etc.);

(iv) Sufficient additional cushioning material is used to take up void spaces and to prevent significant movement of the primary receptacles; and

(v) Primary receptacles are oriented within the secondary packaging in the same manner as in the tested package;
(b) A lesser of the tested primary receptacles, or of the alternative types of primary receptacles identified in (a) above, may be used provided sufficient cushioning is added to fill the void spaces(s) and to prevent significant movement of the primary receptacles.

(from 6.3.2.8)

6.3.5.1.8 Inner receptacles of any type may be assembled within an intermediate (secondary) packaging and transported without testing in the outer packaging under the following conditions:

(a) The intermediate/outer packaging combination shall have been successfully tested in accordance with 6.3.2.3 with fragile (e.g., glass) inner receptacles.

(b) The total combined gross mass of inner receptacles shall not exceed one half of the gross mass of inner receptacles used for the drop test in (a) above.

(c) The thickness of cushioning between inner receptacles and between inner receptacles and the outside of the secondary packaging shall not be reduced below the corresponding thicknesses in the originally tested packaging; and if a single inner receptacle was used in the original test, the thickness of cushioning between inner receptacles shall not be less than the thickness of cushioning between the outside of the secondary packaging and than the thickness of cushioning between the outside of the secondary packaging and the inner receptacle in the original test. When either fewer or smaller inner receptacles are used (as compared to the inner receptacles used in the drop test), sufficient additional cushioning material shall be used to take up the void;

(d) The outer packaging shall have successfully passed the stacking test in 6.1.5.6 while empty. The total mass of identical packages shall be based on the combined mass of inner receptacles used in the drop test in (a) above;

(e) For inner receptacles containing liquids, an adequate quantity of absorbent material to absorb the entire liquid content of the inner receptacles shall be present;

(f) If the outer packaging is intended to contain inner receptacles for liquids and is not leakproof, or is intended to contain inner receptacles for solids and is not siftproof, a means of containing any liquid or solid contents in the event of leakage shall be provided in the form of a leakproof liner, plastics bag or other equally effective means of containment;

(g) In addition to the markings prescribed in 6.3.1.1(a) to (f), packagings shall be marked in accordance with 6.3.1.1(g).

6.3.5.1.9 The competent authority may at any time require proof, by tests in accordance with this section, that serially-produced packagings meet the requirements of the design type tests.

(from 6.1.5.8)

6.3.5.1.10 Provided the validity of the test results is not affected and with the approval of the competent authority, several tests may be made on one sample.

(from 6.1.5.11)
6.3.5.1.11 Preparation of packagings for testing

6.3.2.2 Samples of each packaging shall be prepared as for transport except that a liquid or solid infectious substance shall be replaced by water or, where conditioning at \(-18^\circ\text{C}\) is specified, by water/antifreeze. Each primary receptacle shall be filled to 98\% capacity.

NOTE The term water includes water/antifreeze solution with a minimum specific gravity of 0.95 for testing @ \(-18^\circ\text{C}\).

6.3.5.2.2 Tests and number of samples required

<table>
<thead>
<tr>
<th>Material of outer packaging</th>
<th>Tests required</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>inner packaging</td>
</tr>
<tr>
<td>Fibre-board</td>
<td></td>
</tr>
<tr>
<td>x</td>
<td></td>
</tr>
<tr>
<td>x</td>
<td></td>
</tr>
<tr>
<td>X</td>
<td></td>
</tr>
<tr>
<td>X</td>
<td></td>
</tr>
<tr>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

An alternative approach to this table is shown below.
## Tests required for packaging types

<table>
<thead>
<tr>
<th>Type of packaging</th>
<th>Tests required</th>
<th>No. of samples</th>
<th>No. of samples</th>
<th>No. of samples</th>
<th>No. of samples</th>
<th>No. of samples</th>
<th>No. of samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outer packaging</td>
<td>Inner packaging</td>
<td>Water spray (7.1)</td>
<td>Cold conditioning (7.2)</td>
<td>Drop (7.3)</td>
<td>Additional drop (7.3.3)</td>
<td>Puncture (7.4)</td>
<td>Stack (Annex B)</td>
</tr>
<tr>
<td></td>
<td>Plastics c</td>
<td>Other d</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibreboard box b</td>
<td>Yes</td>
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<td>5</td>
<td>10</td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
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<td>0</td>
<td>5</td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Fibreboard drum c</td>
<td>Yes</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td></td>
<td></td>
<td>2</td>
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<td>2</td>
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<tr>
<td>Plastics box c</td>
<td>Yes</td>
<td>0</td>
<td>5</td>
<td>5</td>
<td>Required on one sample when Packaging is intended to contain dry ice.</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>0</td>
<td>5</td>
<td>5</td>
<td>Required on one sample when testing a “U”-marked packaging as defined in 6.3.5.1.8 for specific provisions</td>
<td></td>
<td>2</td>
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<tr>
<td>Plastics drum c</td>
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<td>0</td>
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<td>3</td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td></td>
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<td>3</td>
<td>3</td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Boxes of other material d</td>
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<td>0</td>
<td>5</td>
<td>5</td>
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<td>2</td>
<td></td>
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<tr>
<td>Drums of other material d</td>
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<td>0</td>
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<td>0</td>
<td>0</td>
<td>3</td>
<td></td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

- Columns A, B and C categorize packagings for test purposes according to their material characteristics and shape.
- The term “fibreboard” shall include similar materials whose performance may be rapidly affected by moisture.
- The term “plastics” relates to materials which may embrittle at low temperature.
- The term “other” relates to other materials such as metal whose performance is not affected by moisture or temperature.

**NOTE 1:** If a primary receptacle and secondary packaging of an inner packaging are made of different materials, the material of the primary receptacle determines the appropriate test.

**NOTE 2:** In instances where a primary receptacle is made of two or more materials, the material most liable to damage determines the appropriate test.

Packagings prepared as for transport shall be subjected to the tests in 6.3.5.3 and 6.3.5.4, which - for test purposes - categorizes packagings according to their material characteristics. For outer packagings, the headings in the table relate to fibreboard or similar materials whose performance may be rapidly affected by moisture; plastics which may embrittle at low temperature; and other materials such as metal whose performance is not affected by moisture or temperature. If a primary receptacle and a secondary packaging of an inner packaging are made of different materials, the material of the primary receptacle determines the appropriate test. In instances where a primary receptacle is made of two materials, the material most liable to damage determines the appropriate test.
Note: The material of the secondary packagings are not taken into consideration when selecting the test or conditioning for the test.

6.3.5.3 Drop test

6.3.5.3.1 Samples shall be subjected to free-fall drops on to a rigid, non-resilient, flat, horizontal surface from a height of 9 m. Where the samples are in the shape of a box; five shall be dropped in sequence:

   (i) flat on the base;
   (ii) flat on the top;
   (iii) flat on the longest side;
   (iv) flat on the shortest side;
   (v) on a corner;

Where the samples are in the shape of a drum, three shall be dropped in sequence:

   (vi) diagonally on the top chime, with the centre of gravity directly above the point of impact;
   (vi) diagonally on the base chime;
   (vii) flat on the side;

Following the appropriate drop sequence, there may be no leakage from the primary receptacle(s) which shall remain protected by cushioning/absorbent material in the secondary packaging;

1 The word cushioning is added because when carrying solids absorbent material is not required

The sample shall be released in the orientation, which for packagings in 6.1 would normally result in an impact on the specified point. It is accepted that over a free fall of 9m the impact may not take place in that orientation.

(This text has been turned from a note to mandatory text. As a note it says, “shall”)

6.3.5.3.2 Special preparation of test sample for the drop test.

6.3.5.3.2.1 Fibreboard outer packagings The sample shall be subjected to a water spray that simulates exposure to rainfall of approximately 5 cm per hour for at least one hour. It shall then be subjected to the test described in (6.3.5.3.1);

6.3.5.3.2.2 Plastics primary or outer packagings The sample shall be conditioned in an atmosphere of –18 °C or less for a period of at least 24 hours and within 15 minutes of removal from that atmosphere be subjected to the test described in (6.3.5.3.1). Where the sample contains dry ice, the conditioning period may be reduced to 4 hours;

6.3.5.3.2.3 Where the packaging is intended to contain dry ice, a test additional to that specified in (6.3.5.3.1) or (6.3.5.3.2.1) or (6.3.5.3.2.1) shall be carried out. One sample shall be stored so that all the dry ice dissipates and then be subjected to the test described in (6.3.5.3.1).

(This text is not clear with one sample what attitude do you use or do you drop in a single sample in every attitude – the packaging would not survive. Since the packaging will have a significant void i.e. no refrigerant is this test necessary?)
6.3.5.4 Puncture Test

6.3.5.4.1 Packagings with a gross mass less than 7kg

A cylindrical steel rod with a mass of at least 7 kg, a diameter not exceeding 38 mm and the impact end edge a radius not exceeding 6 mm. The rod shall be dropped in a vertical free fall from a height of 1 m, measured from the impact end to the impact surface of the sample. One sample shall be placed on its base. A second sample shall be placed in an orientation perpendicular to that used for the first. In each instance the steel rod shall be aimed to impact the primary receptacle. Following each impact, penetration of the secondary packaging is acceptable, provided that there is no leakage from the primary receptacle(s);

6.3.5.4.3 Packagings with a gross mass of more than 7kg

Samples shall be dropped on to the end of a cylindrical steel rod. The rod shall be set vertically in a level hard surface. It shall have a diameter of 38 mm and the edges of the upper end a radius not exceeding 6 mm. The rod shall protrude from the surface a distance at least equal to that between the centre of the primary receptacle(s) and the outer surface of the outer packaging with a minimum of 200 mm. One sample shall be dropped with its top face lowermost in a vertical free fall from a height of 1 m, measured from the top of the steel rod. A second sample shall be dropped from the same height in an orientation perpendicular to that used for the first. In each instance the packaging shall be so orientated that the steel rod would be capable of penetrating the primary receptacle(s). Following each impact, penetration of the secondary packaging is acceptable, provided that there is no leakage from the primary receptacle(s);

(The pass fail criteria in 6.3.2.6 (a) and (b) has been different and (b) has been aligned with (a))

6.3.5.5 Test Report

6.3.5.5.1 A test report containing at least the following particulars shall be drawn up and shall be available to the users of the packaging:

1. Name and address of the test facility;
2. Name and address of applicant (where appropriate);
3. A unique test report identification;
4. Date of the test report;
5. Manufacturer of the packaging;
6. Description of the packaging design type (e.g. dimensions, materials, closures, thickness, etc.), including method of manufacture (e.g. blow moulding) and which may include drawing(s) and/or photograph(s);
7. Maximum capacity;
8. Characteristics of test contents, e.g. viscosity and relative density for liquids and particle size for solids;
9. Test descriptions and results;
10. The test report shall be signed with the name and status of the signatory.

6.3.5.5.2 The test report shall contain statements that the packaging prepared as for transport was tested in accordance with the appropriate requirements of this Chapter and that the use of other packaging methods or components may render it invalid. A copy of the test report shall be available to the competent authority.