



**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****Sixtieth session**

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Item 6 (b) of the provisional agenda

Miscellaneous proposals for amendments to the Model Regulations**on the Transport of Dangerous Goods: packagings, including the use of recycled plastics material****Problems with the practical implementation of P650****Transmitted by the expert from Spain*****Introduction**

1. During the fifty-ninth session of the Sub-Committee of Experts on the Transport of Dangerous Goods held in December 2021, document ST/SG/AC.10/C.3/2021/49 from Spain was introduced to the plenary, and further discussed in a lunch time working group meeting.
2. Some interesting comments and paths forward were suggested during the lunch time working group meeting, and Spain agreed to prepare some draft amendments based on these suggestions that were further discussed among interested parties during an online session of the working group on 22 February 2022, with additional written exchange of comments.
3. Spain is very grateful for the valuable comments, suggestions and interesting discussions and background knowledge received from the different experts in that process.

Analysis

4. For Spain, the objective of the revision of packing instruction P650 is to not change the requirements, specifically those related to testing, but to clarify them, and is the purpose of this document. Nevertheless, this document further explores some changes in the requirements that were suggested by the different members of the working group (see paragraph 17 below).

Capability requirements

5. The working group discussed the implications the capability requirements in (6) and (7)(e) have, specifically if these capability requirements implied the need to regularly and mandatorily carry out the tests to demonstrate that capability.

* A/75/6 (Sect.20), para. 20.51

6. The group reached the agreement that the capability to pass the tests mentioned could be demonstrated easiest by direct testing, or alternatively by means such as engineering analysis, testing with an article of similar mass and size, or other equivalent means.
7. Clarification of this aspect can be done by including a note to the corresponding paragraphs referring to capability requirements (see proposal 1).

Complete package

8. Packing instruction P650 is applicable for the completed package, considering that the three components of the packagings will be available not only for packing and marking, but already for the capacity assessment.
9. This specific aspect is relevant for paragraphs (6) and (7)(e) of P650.
10. For (6) it is essential to have all three components there to be able to carry out the test, or to demonstrate by other means the completed package has the capability to pass the test.
11. For (7)(e) all three components are not needed for testing, but it is essential to pass on the information about which of the component fulfils this requirement.
12. Even if the capability clauses included in (6) and (7)(e) are written in such a way that they apply to the complete package, the usual practice seems to be to use components coming from different manufacturers, searching both for the best quality and the best prices for the different components.
13. The capability to pass the mentioned tests must be ensured by the manufacturer of the packaging. Nevertheless, if the consignor chooses to mix components not tested together, he has to take responsibility for the combination of components used and be able to show that the components have the necessary capabilities.
14. Forming a complete package covering all requirements from P650 should not be a complicated task; the more possible safe combinations, the easier this packaging will be available for all situations and in all countries. Nevertheless, if components are used that have not been evaluated together for the fulfilment of the drop test and pressure test, if needed, a technical evaluation will be necessary, to see if the combination of components used is really still capable to pass the mentioned tests.
15. The most usual variation of the package components is using a different primary receptacle than the one originally used in the capability demonstration. For this case, reference to 4.1.8.5 will help the consignor to be able to value the equivalency of the primary receptacle used.
16. The text of P650 should be adapted to consider these aspects (see proposal 2).

Conditioning prior to testing

17. According to different members of the working group, it was never the intention to include conditioning requirements for the tests that could be done to demonstrate the capability to pass the drop test. Removal of this conditioning requirements could be done by changing the paragraphs referenced in (6) (see proposal 3).

Proposals

18. In the following proposals to amend packing instruction P650, new text is shown underlined and deleted text as ~~stricken through~~.
19. **Proposal 1:** Add the following note under (6) and (7)(e):

“*Note: Capability can be demonstrated by direct testing, or alternatively by means such as engineering analysis, testing with an item of similar mass and size, or other equivalent means.*”

20. **Proposal 2:** Add a second sentence at the end of (12) and include a new (13) to read as follows:

- “(12) Clear instructions on filling and closing such packages shall 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. This shall include information on the capability of the package to successfully pass the drop test specified in subparagraph (6), and information on the capability of primary receptacle or secondary packaging, as applicable, to successfully pass the pressure test specified in subparagraph (7)(e), when required, to enable correct selection of the component parts of the packaging.
- (13) If the consignor selects components whose capability has not been evaluated together to form the complete package, he shall give evidence, at the request of the competent authority, that:
- (a) The different components used are capable of successfully passing the drop test specified in subparagraph (6) when assembled to form the completed package; and
- (b) When required, the primary receptacle or secondary packaging is capable of successfully passing the pressure test specified in subparagraph (7)(e).
- Variations of primary receptacles in accordance with 4.1.8.5, fulfilling subparagraph (b), if needed, are considered equivalent to the original primary receptacle.”

21. Renumber current (13) as (14).

22. **Proposal 3:** Modify the first sentence of (6) and delete the second sentence of this paragraph to read as follows:

- “(6) The completed package shall be capable of successfully passing the drop test in 6.3.5.3.1-4 as specified in 6.3.5.2 of these Regulations at a height of 1.2 m. ~~Following the appropriate drop sequence, there shall be no leakage from the primary receptacle(s) which shall remain protected by absorbent material, when required, in the secondary packaging.”~~

23. **Proposal 4:** Following the secretariat’s guidance, a minor editorial amendment has been made to paragraphs (7), (8) and (9) which include lists of criteria, by adding an "and" at the end of the paragraph before the last one.

24. The complete packing instruction including all proposals mentioned before would read as follows (in December 2021, at the fifty-ninth session of the Sub-Committee, it was already decided to delete the Note in packing instruction P650 under (4), following a proposal contained in informal document 4 of that session):

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 cargo transport units and between cargo 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.</p> <p>(2) The packaging shall consist of at least three components:</p> <ol style="list-style-type: none"> a primary receptacle; a secondary packaging; and an outer packaging <p>of which either the secondary or the outer packaging shall be rigid.</p> <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 mark shall be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm; the 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 "BIOLOGICAL SUBSTANCE, CATEGORY B" in letters at least 6 mm high shall be marked on the outer packaging adjacent to the diamond-shaped mark.</p>		
		
<p>(5) At least one surface of the outer packaging shall have a minimum dimension of 100 mm x 100 mm.</p> <p>(6) The completed package shall be capable of successfully passing the drop test in 6.3.5.3.1-4 as specified in 6.3.5.2 of these Regulations at a height of 1.2 m. Following the appropriate drop sequence, there shall be no leakage from the primary receptacle(s) which shall remain protected by absorbent material, when required, in the secondary packaging.</p>		
<p><u><i>Note: Capability can be demonstrated by direct testing, or alternatively by means such as engineering analysis, testing with an item of similar mass and size, or other equivalent means.</i></u></p>		
<p>(7) For liquid substances</p> <ol style="list-style-type: none"> The primary receptacle(s) shall be leakproof; The secondary packaging shall be leakproof; 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; 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; <u>and</u> The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar). 		
<p><u><i>Note: Capability can be demonstrated by direct testing, or alternatively by means such as engineering analysis, testing with an item of similar mass and size, or other equivalent means.</i></u></p>		
<p>(8) For solid substances</p> <ol style="list-style-type: none"> The primary receptacle(s) shall be sift-proof; The secondary packaging shall be sift-proof; 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; <u>and</u> 		

- (d) 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, shall be used.
- (9) Refrigerated or frozen specimens: Ice, dry ice and liquid nitrogen
- (a) When dry ice or liquid nitrogen is used as a coolant, the requirements of 5.5.3 shall apply. When used, ice shall be placed outside the secondary packagings or in the outer packaging or an overpack. Interior supports shall be provided to secure the secondary packagings in the original position. If ice is used, the outside packaging or overpack shall be leakproof; and
- (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 which could result if refrigeration were lost.
- (10) When packages are placed in an overpack, the package marks required by this packing instruction shall 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 Regulations.
- (12) Clear instructions on filling and closing such packages shall 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. This shall include information on the capability of the package to successfully pass the drop test specified in subparagraph (6), and information on the capability of primary receptacle or secondary packaging, as applicable, to successfully pass the pressure test specified in subparagraph (7)(e), when required, to enable correct selection of the component parts of the packaging.
- (13) If the consignor selects components whose capability has not been evaluated together to form the complete package, he shall give evidence, at the request of the competent authority that:
- (a) The different components used are capable of successfully passing the drop test specified in subparagraph (6) when assembled to form the completed package; and
- (b) When required, the primary receptacle or secondary packaging is capable of successfully passing the pressure test specified in subparagraph (7)(e).
- Variations of primary receptacles in accordance with 4.1.8.5, fulfilling subparagraph b, if needed, are considered equivalent to the original primary receptacle.
- (14) Other dangerous goods shall not be packed in the same packaging as Division 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing 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 Regulations need be met.