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## Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

1 June 2021

### Sub-Committee of Experts on the Transport of Dangerous Goods

#### Fifty-eighth session

Geneva, 28 June-2 July 2021

Item 3 of the provisional agenda

#### Listing, classification and packing

## Problems with the practical implementation of P650

### Transmitted by the expert from Spain

#### Introduction

1. During the last year there has been a big increase in transport of UN 3373 “BIOLOGICAL SUBSTANCE, CATEGORY B”, linked to the transport of samples due to testing against COVID-19. This situation has introduced into the transport chain many consignors and transport companies that traditionally have not been transporting biological products and the Spanish experts have witnessed some practices for the transport of UN 3373 related to an improper application of packing instruction P650.

#### Discussion

2. Transport under UN 3373 covers a wide range of substances that shall be transported, for example diagnostic specimens assigned to UN 3373 which are human or animal materials that are being transported only for the purpose of diagnosis or investigation. Such materials may include excreta, blood and its components, tissue samples of all kinds (fresh, fixed in formalin or embedded in paraffin), DNA extracted from blood / tissue, citrated or EDTA blood, serum, plasma, bone marrow, urine, saliva, cerebrospinal fluid, maternal blood, biopsies of all kinds, hair, nails, exudates of all kinds, cell lines of all kinds, immunoglobulins, bacterial or viral strains (lyophilized, frozen, refrigerated), respiratory samples of SARS CoV2 (nasal exudate, nasal swab, bronchial aspirate... ), recombinant antibodies, proteins, as well as other tissues and fluids.

3. Transport of UN 3373 shall be done only according to P650, and not to any additional general requirements included into other parts of the Model Regulations (see special provision 319). This inter alia means that the packaging defined in P650 has no UN mark and therefore is not handled, from the point of view of control and approval, as other packagings.

4. A package according to P650 shall consist of three components (see figure 1):

- (a) a primary receptacle;
- (b) a secondary packaging; and
- (c) an outer packaging.

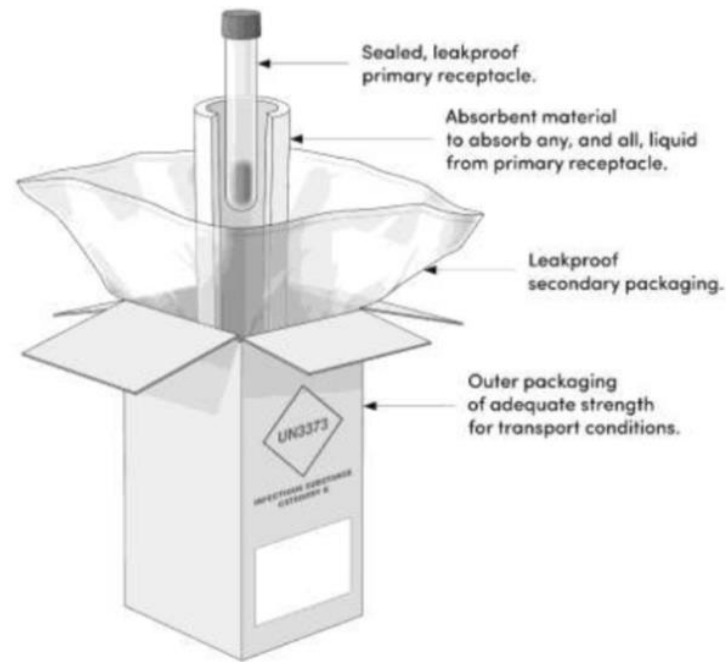


Figure 1: Triple packaging for UN 3373 (Source: *Guidance on regulations for the transport of infectious substances 2019– 2020. WHO/WHE/CPI/2019.20 World Health Organization 2019*)

5. Of the different requirements included in P650, the Spanish experts would like to specifically focus on the drop test and the pressure test. According to P650 (6), the complete package (including all three components) shall pass a drop test. Additionally, the pressure test according to P650 (7e) (mandatory for transport of liquids) can be either carried out on the primary receptacle, or on the secondary packaging.

6. Many different primary receptacles are designed for many different uses (see paragraph 2 above), adapting to the different size and properties of the biological material to be transported. Therefore, primary receptacles have differing forms and are needed for different purposes, adapting the material, shape and closing system to the specific need (see figure 2).



Test tubes. *Diagnosis use.*



Petri dish. *Cultures use*



Urine collection cup.  
*Urine tests use.*



Falcon Tube *Cultures use*



Eppendorf Tube: *Diagnosis use.*



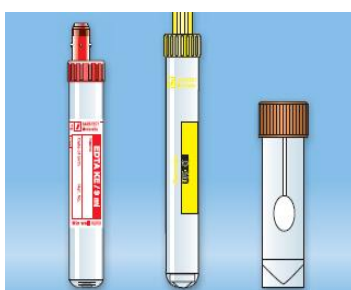
Assaig Tube: *Diagnosis use*

*Figure 2: Different primary receptacles*

7. To fulfill the criteria established in P650 (6), the manufacturer of the packaging could pass the drop test with a secondary and outer packaging, containing different primaries receptacles, to adapt to this variety in primary receptacles.

8. Additionally, the pressure test indicated in P650 (7e) could be passed alternatively with the secondary packaging, or with all the single different primary receptacles that are needed.

9. Nevertheless, it seems quite common that the primary receptacle is not provided by the manufacturer of the secondary and outer packaging. This makes it impossible to know if the complete package would pass the drop test as mentioned in P650 (6). Additional difficulties arise when, for example, the consignor has not the information if the manufacturer has passed the pressure test with the primary receptacle or with the secondary packaging, so he can end up making unsafe combinations mixing primary and secondary receptacles where none of both has passed the pressure test (see figures 3 and 4).



*Figure 3: Primary receptacles used not provided by the packaging manufacturer of secondary and outer packaging. (Source: ANSBIO, National Association for Biological Safety in the Logistics Chain)*



Figure 4: Secondary and outer receptacles provided by the same packaging manufacturer.  
(Source: ANSBIO, National Association for Biological Safety in the Logistics Chain)

10. In reference to the pressure test, the pressure is easier to resist with a smaller receptacle, and therefore most pressure tests are done with primary receptacles. Also some designs pass the pressure test with the secondary packaging; but this is not the usual situation.

11. Nevertheless, most cases of primary receptacles found in real transport situations are not primary receptacles that would resist a pressure test, as they don't have a screw tap. Also, most cases found in real transport situations are also not pressure resistant (see figures 6 to 10).



Figure 5: Primary receptacle. Pressure test resistant glass tube with screw tap and sealing ring. (Source: Testing laboratory AIDIMME)



Figure 6: Primary receptacle. Non-pressure test-resistant tube with screw tap without sealing ring. (Source: Testing laboratory AIDIMME)



Figure 7: Primary receptacle. Non-pressure test-resistant tube without screw tap. (Source: Testing laboratory AIDIMME)



Figure 8: Secondary packagings, non pressure resistant (Source: Testing laboratory AIDIMME)



Figure 9: Secondary packagings, non pressure resistant (Source: ANSBIO, National Association for Biological Safety in the Logistics Chain)

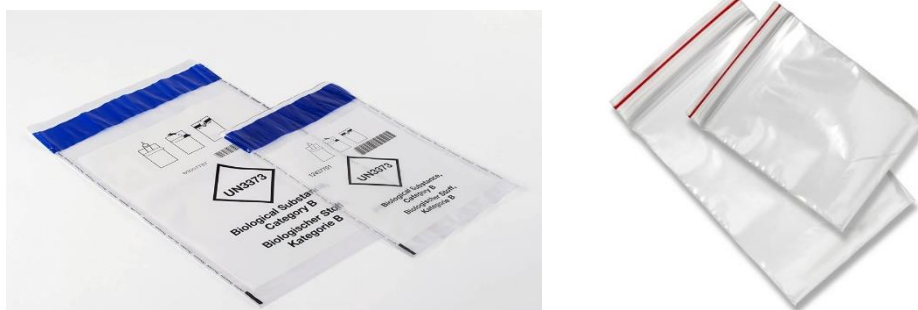


Figure 10: Secondary packagings, non pressure resistant (Source: ANSBIO, National Association for Biological Safety in the Logistics Chain)

12. Primary receptacle with a screwed closing, having an enough screw longitude and a sealing ring, resisting the pressure test are very expensive, the price is around 20 times the price of a not-pressure-test-resistant closing. This makes the use of tested primary receptacles very uncommon.

13. In transport situations, in most cases, the primary receptacles used have not been tested according to P 650 (7e). So it seems to be current practice to pass the pressure test with one primary receptacle, but sell/provide/use other primary receptacles, that have not been tested, and are less expensive.

14. Additionally, if the three parts of packaging are not provided by the same manufacturer, for the consignor, without expertise, it is very difficult to check if the pressure test has been passed or not. And the combination of the three packagings will not have been testes according to P650 (6).

## Action Requested

15. Spain has observed some difficulties in the transport of UN 3373 according to P650, specifically in the use of packaging combinations that have not been correctly tested according to P650. Spain would like to know if other countries have also observed infringements and would like to know how these issues have been solved.

16. Taking into consideration the high number of this type of consignments transported currently, and the situations found normally in transport, it could be necessary to review the conditions of the transport under P650. Specifically, it could be interesting to clearly modify the pressure test requirement so that always the secondary packaging shall fulfil this requirement.

## Proposal

17. Modify P650 (7e) by indicating clearly that the pressure tests for liquid contents shall be passed with the secondary receptacle. Deleted text is shown as ~~sticken through~~.

P650

## PACKING INSTRUCTION

P650

This packing instruction applies to UN 3373.

- (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.
- (2) The packaging shall consist of at least three components:
  - (a) a primary receptacle;
  - (b) a secondary packaging; and
  - (c) an outer packaging
 of which either the secondary or the outer packaging shall be rigid.
- (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.
- (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.



**NOTE:** The mark shown in paragraph (4) of Packing Instruction P650 of the seventeenth revised edition of the Recommendations on the Transport of Dangerous Goods, Model Regulations may continue to be applied until 31 December 2016.

- (5) At least one surface of the outer packaging shall have a minimum dimension of 100 mm × 100 mm.
- (6) The completed package shall be capable of successfully passing the drop test in 6.3.5.3 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.

- (7) For liquid substances
- (a) The primary receptacle(s) shall be leakproof;
  - (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).
- (8) For solid substances
- (a) The primary receptacle(s) shall be siftproof;
  - (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) 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;
  - (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.
- (13) 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.

**Additional requirement:**

Alternative packagings for the transport of animal material may be authorized by the competent authority in accordance with the provisions of 4.1.3.7.