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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

Sub-Committee of Experts on the Transport of Dangerous Goods

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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 packing instruction P650

Transmitted by the expert from Spain*

Introduction

1. Transport of UN 3373 “BIOLOGICAL SUBSTANCE, CATEGORY B” is only subject to the conditions imposed in packing instruction P650. Spanish experts have witnessed repeated cases of improper application of packing instruction P650, partially linked to the transport of samples due to testing of COVID-19.

2. Attention was already drawn on this problem through informal document INF.9 presented at the June 2021 session of the Sub-Committee. During the discussion no consensus on the proposed amendment to P650 could be reached, but several delegations pointed to different aspects of P650 that could be interesting to further analyse, and if needed, updated the proposal.

Discussion

3. Transport under UN 3373 covers a wide range of substances that must be transported, as diagnostic specimens from human or animal origin that are being transported 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 (deoxyribonucleic acid) extracted from blood or tissue, serum, plasma, bone marrow, urine, saliva, cerebrospinal fluid, maternal biopsies, hair, nails, exudates, cell lines, immunoglobulins, bacterial or viral strains (lyophilized, frozen, refrigerated), respiratory samples of virus SARS CoV-2 (nasal exudate, nasal swab, bronchial aspirate, etc.), recombinant antibodies, proteins, as well as other tissues and fluids.

4. Transport of UN 3373 shall be done only according to packing instruction P650, and not to any additional general requirements included into other parts of the UN Model

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

Regulations (see paragraph (11) of P650 and 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 quality-control and approval, as other packagings.

5. According to the discussions on this subject during the previous session of the Sub-Committee, different aspects of P650 could be worth to be analysed in more detail, to see if different interpretations and/or problems of application have appeared in different countries and/or transport modes:

- Drop test
- Pressure test
- Information provided for the consignor

6. It should be noted that P650 provides an increased safety compared to those transports according to 2.6.3.2.3.8 for human or animal specimens for which there is minimal likelihood that pathogens are present, safety that is enhanced by the drop test and pressure test included into the P650 requirements.

Drop test

7. During the discussions, one delegation mentioned that the packages must have the capability to withstand the drop test, but this does not necessarily mean that the tests had to be passed systematically.

8. Nevertheless, reading the text of P650 even if it is indicated that the '*completed package shall be capable of successfully passing the drop test*', the rest of the paragraph seems to imply that a drop test must be performed; especially with the wording of the last sentence: "*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"* and the reference to 6.3.5.3 (drop test) and 6.3.5.2 (preparation for packagings for testing). It would be difficult for a user to make the determination that the packaging can pass the drop test, without actually doing one, in particular when the preparation and conditioning clauses are invoked.

9. The wording of the different language versions is not helpful to clarify this aspect. The English version "The completed package shall be capable of successfully passing the drop test in 6.3.5.3…" and the French version "Le colis complet doit pouvoir subir avec succès l'épreuve de chute du 6.3.5.3…" indicates the capability, while the Spanish version includes a clear obligation to pass the tests "El bulto completo deberá superar con éxito el ensayo de caída de 6.3.5.3…" meaning that "The completed package shall pass with success the drop test of 6.3.5.3…)".

10. It would be good to have a clear view if the drop test should or not be performed systematically, to have similar requirements imposed on all packages. Wording of the different language versions should be adapted to clarify the need, or not, to perform the test.

Pressure test - information on the passed tests

11. As already mentioned in INF.9 referred to above, the pressure test according to packing instruction P650 (7e) (mandatory for transport of liquids) can be either carried out on the primary receptacle or on the secondary packaging.

12. As many different primary receptacles are used, the pressure test indicated in packing instruction P650 (7e) could be passed alternatively with the secondary packaging, or with all the single different primary receptacles that are needed.

13. Nevertheless, it seems quite common that the primary receptacle is not provided by the manufacturer of the secondary and outer packaging. Without information on this aspect, the consignor has no information on whether 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.

14. Therefore, the consignor may need additional information to take appropriate decisions.

15. For this test, it would be good to have a confirmation that “shall be capable to withstand, without leakage, an internal pressure” necessarily implies the need to carry out the tests. A clearer wording in all language versions would be helpful.

Pressure test - testing procedure

16. The Technical Instructions of International Civil Aviation Organization (ICAO) include additional wording on the pressure test, namely the following:

> *"**Note**: The capability of a packaging to withstand an internal pressure without leakage that produces the specified pressure differential should be determined by testing samples of primary receptacles or secondary packagings. Pressure differential is the difference between the pressure exerted on the inside of the receptacle or packaging and the pressure on the outside. The appropriate test method should be selected based on receptacle or packaging type. Acceptable test methods include any method that produces the required pressure differential between the inside and outside of a primary receptacle or a secondary packaging. The test may be conducted using internal hydraulic or pneumatic pressure (gauge) or external vacuum test methods. Internal hydraulic or pneumatic pressure can be applied in most cases as the required pressure differential can be achieved under most circumstances. An external vacuum test is not acceptable if the specified pressure differential is not achieved and maintained. The external vacuum test is a generally acceptable method for rigid receptacles and packagings but is not normally acceptable for:*
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> - *flexible receptacles and flexible packagings;*
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> - *receptacles and packagings filled and closed under an absolute atmospheric pressure lower than 95 kPa."*

17. It may be interesting to analyse if a part, or all, of the indications on the pressure test should also be included into the UN Model Regulations.

Information provided for the consignor

18. According to paragraph (12) of packing instruction P650, the packaging must have clear instructions for filling and closing the packages for the consignor or the person who prepares the package (e.g. patient).

19. Additional information should be included, specifying clearly which components the complete package consist of.

20. If the consignor is sourcing components from different suppliers, the consignor must ensure the requirements of the packaging, once assembled, meets the requirements for P650 packaging and, therefore, this information included with the package should perhaps include information on whether the component has been pressure tested. Including here information on the drop test would be a way, for the consignor, to check if the drop test has been done, and which possibilities of combining components exist.

21. An amendment to P650 (12) could be discussed, according to which information about the internal pressure test of the primary receptacle or the secondary packaging or the drop test should also be provided.

22. In the case a patient is directly preparing the package, additional information would only be confusing. Nevertheless, the patient would more be a packer than a real consignor, as the package components are given to the patient in advance by a medical or transport company. Therefore, it would perhaps be better to include this additional information requirement in a separate paragraph of P650.

Proposal

23. Spain would welcome a lunch time working group meeting to be held during the Sub-Committee's session to further discuss different aspects of P650 with interested parties and discuss the need for further work to be done on this packing instruction.