

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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MISCELLANEOUS PROPOSALS OF AMENDMENTS TO THE MODEL REGULATIONS

Infectious substances

Transmitted by the expert from Canada

Background

Sections 2.6.3.2.3 to 2.6.3.2.5 of the 13th Edition of the Model Regulations pertain to the applicability of the requirements in the Model Regulations for transporting infectious substances. While these sections are intended to provide exemptions from the requirements of the Model Regulations it is believed that, as a result of many questions and comments received in different fora, these sections could be clarified.

In addition, the documentation requirements for UN2814 and UN2900, could be clarified to indicate who a responsible person is and what that person should be able to do.

Finally, Special Provision 319 which is against the entry for UN3373 also requires clarification to ensure understanding on the part of consignors, carriers and others that the description relates to Category B infectious substances and not to any other substances.

This paper is submitted to the Sub-Committee to request comments and suggestions with a view to the development of a formal paper for the July meeting.

Proposal Number 1

Proposal No. 1 is to delete the existing text in 2.6.3.2.5 to 2.6.3.2.6 and to replace it with the following text. It should be noted that the proposed text has some editorial changes in it but the concepts are not substantively different from the existing text. The existing sections have been re-arranged and notes referencing the existing text are provided for ease of reference.

2.6.3.2.3 *Substances not subject to these Regulations*

2.6.3.2.3.1 Substances that do not contain infectious substances (*Note: see current 2.6.3.2.3*) or substances that have been treated so that the pathogens have been neutralized or inactivated so that they no longer pose a health risk are not subject to these Regulations unless they meet the criteria for inclusion in another class. (*Note: See current 2.6.3.2.5*)

2.6.3.2.3.2 Tissues or organs approved for transplant are not subject to these Regulations. (*Note: See current 2.6.3.2.4.*)

2.6.3.2.3.3 Substances where the concentration of pathogens is at a level naturally encountered are not subject to these Regulations. Examples include foodstuffs and water samples. (*Note: See current 2.6.3.2.5. Reference to "living persons" removed*)

2.6.3.2.3.4 Dried blood spots, collected by applying a few drops of blood onto specially manufactured absorbent filter paper and air dried, are not subject to these Regulations. (*New*)

2.6.3.2.3.5 The national competent authority of a country may regulate the transport of medical samples in a manner that is not consistent with these Regulations provided such medical samples are transported exclusively within the borders of that country. (*New*)

2.6.3.2.4 *Substances not subject to these Regulations if they are packaged in accordance with this section*

2.6.3.2.4.1 Substances that are unlikely to cause disease in humans or animals (*Note: See current 2.6.3.2.3*) or substances that are believed not to contain infectious substances (*Note: See current 2.6.3.2.5*) in Category A or Category B are not subject to these Regulations if they do not meet the criteria for inclusion in another class and are packaged in accordance with 2.6.3.2.4.3. Determination of substances that are exempt under this section should be based on the known medical history and symptoms of the patient, endemic local conditions or professional judgement concerning the individual circumstances of the patient.

2.6.3.2.4.2 Blood or blood components that have been approved for transfusion or transplantation or approved for the preparation of blood products to be used for transfusion or transplantation (*Note: See current 2.6.3.2.4*) are not subject to these Regulations if the blood or blood components are packaged in accordance with 2.6.3.2.4.3

2.6.3.2.4.3 The substances referred to in 2.6.3.2.4.1 and the blood or blood components referred to in 2.6.3.2.4.2 shall be contained in a packaging that

- (a) is in compliance with packing instruction P650, except that the marking requirement in section (4) of that packing instruction does not apply; or
- (b) is designed, constructed, filled, closed, secured and maintained so that under normal conditions of transport there will be no leakage or spillage of the substance or of the blood or blood components; for liquid substances in fragile primary receptacles (such as glass, porcelain, stoneware, blood bags, certain plastics), the packaging shall have cushioning material to prevent breakage and shall have absorbent material sufficient to absorb the entire contents.

Proposal Number 2

Delete the existing section 2.6.3.2.6, move it to the end of Chapter 2.6 and renumber the section.

2.6.3.6 *Live infected animals*

2.6.3.6.1 A live animal that has been intentionally infected and that is known or believed to contain an infectious substance shall only be transported under terms and conditions approved by the appropriate national authority.

Proposal Number 3

This proposal is to replace the existing text of 5.4.1.5.6 with the following text. It should be noted that this requirements applies only to UN2814 and UN2900:

5.4.1.5.6 *Infectious Substances*

The transport document shall include the telephone number where the consignor is readily available to give technical or emergency response information about the infectious substances. The name and telephone number of a person who is not the consignor may be shown instead on the transport document if the person can provide the same level of technical or emergency response information that the consignor would provide.

Reason

The existing text does not specify who the "responsible" person should be or what that person should be able to do. Consequently, to comply with this requirement, a consignor can simply select a person he or she knows to be responsible (but not necessarily knowledgeable about the substances) and include the name and telephone number of the person on the document.

Proposal Number 4

This proposal is to change the text of Special Provision 319 as follows – note that the added text is written in bold and is underlined, text to be deleted is indicated by strikeout:

319 This entry applies to human or animal material **that contain Category B infectious substances** including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, and body parts. ~~being transported for purposes such as research, diagnosis, investigational activities, disease treatment or prevention.~~ **Category B infectious** substances packed and marked in accordance with packing instruction P650 are not subject to any other requirements in these Regulations.

Reason

The current wording of Special Provision 319 is not clear despite the fact that it is against the entry for UN3373. Category B can include diagnostic specimens that contain infectious substances yet substances, for example, that are not believed to contain Category B substances or that are known not to contain Category B substances can also be in diagnostic specimens. The result is confusion and lack of understanding. In addition, the purpose for the transport of Category B substances seems to be unnecessary and it is suggested that these words be deleted.
