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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

Twenty-fifth session, 5-14 July 2004
Item 7 of the provisional agenda

MISCELLANEOUS PROPOSALS OF AMENDMENTS TO THE MODEL REGULATIONS

Interpretation questions regarding infectious substances

Transmitted by the expert from the Netherlands

Background

During the last session in December 2003, the expert from Canada proposed new amendments to some of the provisions concerning infectious substances in order to clarify the interpretation of these provisions. At that time all delegations were invited to provide the expert from Canada with written comments so that all concerns with the existing texts could be addressed at the next session (paras. 84-89 ST/SG/AC.10/C.3/48).

In view of this invitation and the preparation for the implementation of the recently revised provisions the Ministry of Transport has been in contact with the relevant Dutch ministries and sectors for medical and animal health, waste, labor health and carriage by post. They have presented important interpretation questions, to which we would like to draw the attention of the Subcommittee.

The Netherlands is aware of the wish expressed by several delegations during the last session that the finalization of the revision concerning infectious substances should take place in the current biennium. Therefore, an answer by the Subcommittee to the questions presented in this document would be preferable during this session. These answers are important to avoid confusion and in the worst case incorrect application or non-compliance of the provisions in practice.

Some of the questions have been inspired by a consultation document by Canada, and the subsequent reactions by several delegations (e.g. United States of America, Germany).

Document in general

The Netherlands have no intention to affect the overall intention of the 6.2 provisions. As stated before, the reason for this document are interpretation questions.

For a quick understanding and reading of this document the questions have been ranged from substantial interpretation and enforcement questions to suggestions for editorials that could improve user-friendliness. Whether it concerns substantial or editorial text will be indicated in the heading of each question.

In general the questions concern:

1. definitions
2. classification
3. exemptions
4. medical and clinical wastes
5. other relevant provisions
6. other related international bodies

1. Substantial, clarity on the scope of application of the provisions

2.6.3.1.1 (definition infectious substance)

In the definition of infectious substances it is stated that a substance is infectious when it contains pathogens, which can cause disease in humans or animals. We have understood that the main factor in the determination of a substance as an infectious substance is the risk of transmission during transport. The medical sector has presented several examples where the risk of transmission during transport is virtually absent, such as dried blood spots, cups with a few drops of blood to test on diabetes, trombosis etc.. This leads the Netherlands to the conclusion that such examples are not infectious substances and are not subject to the class 6.2 provisions.

⇒ *Does agreement exist on the interpretation that human or animal diagnostic or clinical specimen collected for routine-testing and for which there is no reason to suspect that it is an infectious substance, are not subject to the provisions of class 6.2?*

If this is the case, we would suggest to make a clear and separate exemption for human or animal clinical specimens that have been collected for routine-testing and for which there is no reason to suspect that it is an infectious substance (See also question 2)

⇒ *Does agreement exist for inclusion of an explicit exemption for clinical specimen collected for routine-testing and for which there is no reason to suspect that it is an infectious substance?*

2. Substantial and editorial, to improve user-friendliness

2.6.3.2.3 (exemptions)

In the current provisions, it is difficult to have a direct overview on the different exemptions. A heading and an enumeration might facilitate a quick understanding of the applicable provisions and reduce questions on this issue.

For example by replacing the current 2.6.3.2.3 by the following provision, which would include 2.6.3.2.3. itself and 2.6.3.2.5 and a renumbering of 2.6.3.2.4 and 2.6.3.2.6 accordingly.

⇒ *Does agreement exist to include a heading and enumeration for the exemptions? An example is given below:*

The following example text is based on a common position with Canada:

"2.6.3.2.3 Substances not subject to these Regulations

2.6.3.2.3.1The following substances are not subject to these Regulations unless they meet the criteria for inclusion in another class:

(a) Substances that are being transported for diagnostic purposes, other than to determine if an infectious substance is present, and for which there is no reason to suspect that an infectious substance is present (new);

***NOTE**: Professional judgement is required to determine substances that are exempt under this paragraph and should be based on the known medical history, the symptoms, the individual circumstances and the endemic local conditions of human, animal or source. Examples of substances that could be included in this section are those being sent for testing the presence of drugs alcohol or to determine cholesterol or blood glucose levels.*

(b) Substances that are non-pathogenic to humans or animals; or

(c) Substances for which there is a low probability that they are pathogenic to humans or animals;

(d) Substances or materials where the concentration of the infectious substance is at a level naturally encountered;

***NOTE**: Examples of these substances include foodstuffs, water, soil or dust samples.*

(e) Substances that have been treated so that the pathogens have been inactivated and no longer pose a health risk"

In this text, the exemptions for transfusion and transplantation, the provision for alive animals and the exemption for certain biological products would each keep their own provision (current 2.6.3.2.4, 2.6.3.2.6 and 2.6.3.3.1 (a)).

3. Substantial, clarity on the scope of application of the provisions

2.6.3.1.3 (cultures)

Questions have been raised on one part of the definition regarding *"cultures"*. "Cultures for diagnostic and clinical purposes" are excluded from the definition, but the provisions do not provide an explicit indication on how these cultures should the classified.

We have assumed that cultures for diagnostic and clinical purposes would fall under Category B infectious substances. Is this assumption correct? If so, we would suggest to mention this explicitly in the provisions, for example at the end of 2.6.3.2.2.2.).

⇒ *Does agreement exist on the interpretation that cultures for diagnostic and clinical purposes fall under Category B infectious substances?*

⇒ *Does agreement exist on the inclusion of an explicit provision or note on the classification of cultures for diagnostic and clinical purpose?*

4. Substantial, clarity on the classification of medical or clinical waste

2.6.3.2.1 (classification infectious substance)

Not only UN 2814, UN 2900 and UN 3373 may be infectious substances. As is made clear in the current provision 2.6.3.5.1, this may also be the case for UN 3291 clinical waste unspecified n.o.s. or (bio) medical waste n.o.s. or regulated medical waste n.o.s. We would suggest to insert UN 3291 in paragraph 2.6.3.2.1. to read:

"2.6.3.2.1Infectious substances shall be classified in Division 6.2 and assigned to UN 2814, UN 2900, UN 3291 or UN 3373 as appropriate."

⇒ *Does agreement exist on the insertion of "UN 3291" in provision 2.6.3.2.1 as mentioned above?*

5. Substantial, clarity on the scope of application of the provisions

2.6.3.2.2.1 (Category A)

The first sentence *'transported in a form that'* in 2.6.3.2.2.1 has given rise to confusion whether it refers to transport or transmission and as to what is meant by "a form". To avoid this confusion the underlined addition could be made:

"An infectious substance which is transported in a <u>transmittable</u> form <u>(such as cultures)</u> that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals."

⇒ *Does agreement exist on the insertion of 'transmittable' and 'such as cultures' in the description for Categorie A as mentioned above?*

6. Substantial, interpretation question concerning the scope of UN 3291

2.6.3.5.2 (assignment to UN 3291)

Questions have arisen on the scope of UN 3291. From 2.6.3.5.1 follows that wastes which do contain infectious substances (of Category B), can be assigned to UN 3291 while at the same time it is stated in 2.6.3.5.2. that wastes which do probably not contain infectious substances can also be assigned to UN 3291.
If the interpretation is that the two above-mentioned types of wastes should be assigned to UN 3291, an enumeration of these types could avoid confusion on this matter.

For example:

"2.6.3.5.2. The following wastes shall be asigned to UN 3291:

(a) medical or clinical wastes containing infectious substances in Category B, other than cultures.
(b) medical or clinical wastes which are reasonable believed to have a low probability of containing infectious substances."

⇒ *Does agreement exist on the above-mentioned interpretation?*

⇒ *Does agreement exist on the inclusion of a text such as given in the example?*

7. Enforcement question

2.6.3.5.3 and 2.6.3.2.5 (decontaminated medical or clinical wastes and neutralized or deactivated pathogens)

By the dutch inspectorate for the transport regulations, questions have arisen concerning the decontamination of medical and clinical waste and more in general the deactivation of pathogens. Decontaminated waste and substances of which the pathogens are neutralized or inactivated are exempted from the class 6.2 provisions. However, for enforcement authorities it is difficult to determine whether the waste is actually decontaminated, especially as there is no requirement for a decontamination certification.

⇒ *How do the enforcement authorities of other countries deal with this issue?*

8. Editorial, user-friendliness

2.6.3.5.1 (medical and clinical wastes)

The current text in 2.6.3.5.1 concerning medical and clinical wastes gives rise to confusion whether a substance has to be assigned to Category A or B; UN number UN 2814, UN 2900 or UN3291. An enumeration could make the text more user-friendly. For example:

"2.6.3.5.1 Medical or clinical wastes:
- in cultures (laboratory stocks) are assigned to Cat. A or Cat. B substances and UN 2814 or UN 2900 as appropriate;
- not in cultures (laboratory stocks) are assigned to Cat. A and UN 2814 and UN 2900 as appropriate, or are assigned to Cat. B and UN 3291".

⇒ *Does agreement exist on the insertion of a more user-friendly text, for example as mentioned above?*

9. Editorial, user-friendliness

2.6.3.2.6 (live animals)

Questions arise concerning the applicable provisions on the transport of live animals. In chapter 2.6 there is a provision on the transport of live animals (2.6.3.2.6) as is in chapter 5 (5.5.1.1). The text differs slightly.

Is it possible to delete one of the provisions so that no confusion can arise as to the applicable provision concerning the transport of live animals? The current text in paragraph 5.5.1.1 might be preferable because of its clarity.

⇒ *Does agreement exist on the deletion of one of the provisions as mentioned above?*

10. Editorial, user-friendliness

7.1.6.2 and 4.3.2.4 (other relevant provisions)

Users of the Model Regulations experience some difficulty in finding all relevant provisions concerning class 6.2 in the Model Regulations. This is especially the case for users in the medical sector, postal transport, labor safety and others who are not familiar with the transport legislation.

A reference in chapter 2.6 to other relevant provisions could make the provisions in total more user-friendly. For example by making a reference to the applicable provisions concerning transport operations in paragraph 7.1.6.2 and the applicable provisions concerning bulk transport of UN2900 in paragraph 4.3.2.4.

⇒ *Does agreement exist to make a reference to other relevant provisions as mentioned above?*

11. Editorial, user-friendliness

2.6.3.1 (definitions)

The Netherlands think that user-friendliness could be improved by either making a reference to the definitions mentioned in 2.6.3.1 in Chapter 1.2 or by repeating the definitions in that Chapter. In order to avoid additional text, we would suggest to make a reference.

⇒ *Does agreement exist on making a reference to the definitions as mentioned above?*

12. Related international bodies

The Secretariat is asked to inform the related international bodies the results of these interpretation questions, as is done for the International Organization for Animal Health (OIE), so that these organizations may take notice of the outcome of the discussion for their specific legislation. For example the Universal Postal Union (UPU), the International Labor Organization (ILO) and the EU body concerned with labor safety.
