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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  
ON THE TRANSPORT OF DANGEROUS GOODS**

Infectious substances

Transmitted by the expert from Canada

**Background**

1. In early February, the expert from Canada sent a Consultation Document to the Sub-Committee for comment on proposed clarifications to various sections in the 13th Edition of the Model Regulations that relate to the requirements for transporting infectious substances. The expert from Canada is grateful to those who sent comments. However, as expected, those comments were wide ranging and trying to find a level of agreement was difficult.
2. Having said that, in reviewing the comments carefully a number of times it seemed possible to concentrate on some areas where agreement appeared to be achievable. This paper proposes changes to those areas.
3. This paper contains three proposals for the consideration of the Sub-Committee.

**Proposal Number 1**

Some commenters on the February consultation document suggested that the current text of 2.6.3.2.3 and 2.6.3.2.4 is satisfactory and should not be changed. Consequently, Proposal Number 1 focuses on 2.6.3.2.5 and 2.6.3.2.6.

It is proposed to itemize the exemptions in 2.6.3.2.5 as follows and to propose some editorial changes primarily based on the comments received on the February consultation document in an attempt to clarify the exemptions in this section:

2.6.3.2.5 The 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, except to determine if an infectious substance is present, and for which there is no reason to suspect, other than through statistical inference, that an infectious substance is present;

*Note: Professional judgement is required to determine whether or not substances are exempt under this paragraph and should be based on the known medical history and symptoms of the source human or animal, endemic local conditions and the individual circumstances of the source human or animal (e.g., medical history). Examples of substances that could be included in this section are those being sent for testing for the presence of drugs or alcohol or to determine cholesterol or blood glucose levels.*

- (b) substances or materials where the concentration of pathogens is at a level naturally encountered;

*Note: Examples of these substances include foodstuffs, water, soil or dust samples. (Note: See current 2.6.3.2.5).*

- (c) substances which have been treated so that the pathogens have been inactivated and no longer pose a health risk; and
- (d) dried blood spots, collected by applying a drop of blood onto absorbent material and specimens for faecal screening tests. *(New)*

**It is further proposed to change the current wording of 2.6.3.2.6 to the following and, if this proposed change is accepted, 5.5.1.1 would be deleted:**

**2.6.3.2.6** Unless an infectious substance cannot be consigned by any other means, live animals shall not be used to consign such a substance. *(Note: the underlined sentence is the text of 5.5.1.1)* A live animal that has been intentionally infected and that is known or suspected to contain an infectious substance shall only be transported under terms and conditions approved by the competent authority.

### **Reason**

Deleting section 5.5.1.1 and placing the text with 2.6.3.2.6 groups the two sections together in one place, is more user friendly and emphasizes the requirements regarding the transport of such animals.

## **Proposal Number 2**

**This proposal contains two options.**

### **Option 1**

Delete special provision 319. The need for special provision 319 is questionable and, while it provides information, that same information could also apply to UN2814 and UN2900 so why it is necessary for UN3373. In addition, the last sentence in the special provision is already in P650.

### **Option 2**

**If the Sub-Committee does not agree with deleting special provision 319 then, in the opinion of the Expert from Canada, the text needs to be clarified and the following is proposed - note that the added text is underlined:**

319 This entry applies to substances that contain or articles contaminated with 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. Substances packed and marked in accordance with packing instruction P650 are not subject to any other requirements in these Regulations.

### **Reason**

**The reason for suggesting a clarification to the text of special provision 319 is that the current wording is not clear despite the fact that it is against the entry for UN3373. The difficulty arises from the shipping name for Category B which can include diagnostic specimens that contain Category B infectious substances or articles that are contaminated with Category B infectious substances, yet substances referred to in 2.6.3.2.5 above that are not suspected of containing infectious substances, other than through statistical inference, can also be in diagnostic specimens. The result is confusion and lack of understanding.**

**In addition, the words "articles contaminated with" have been added to try to clarify the use of UN3373 in response to INF 60 submitted to the Sub-Committee in December by Dr. David Gilabert, Switzerland.**

**It should be noted that some commenters felt that the text of special provision 319 could be deleted and placed in the text following 2.6.3.2.2.2. This suggestion has not been proposed because the current text of Special Provision 319, except for the last sentence, could just as easily apply to Category A so the relevance of retaining it as text following 2.6.3.2.2.2 was not clear.**

## **Proposal Number 3**

The shipping name for UN3373, "Diagnostic Specimen" or "Clinical Specimen" has caused confusion in that people see a shipping name associated with a UN number but also recognize that the samples referred to in 2.6.3.2.5 above are called by most consignors and carriers "diagnostic specimens". So, for many consignors and carriers, the words "diagnostic specimen" in the shipping name for UN3373 blurs the lines between those substances that are regulated and those substances that are not intended to be regulated. In addition, the Secretary has pointed out that the current shipping name is not appropriate for large volumes of blood collected at abattoirs and transported for processing purposes.

It is recognized that the problem of the shipping name for UN3373 is, at the moment, most critical for air transport. The UN Model Regulations do not require a document for UN3373 or that the shipping name be marked on the package. The 2005/2006 ICAO Technical Instructions require the shipping name for UN3373 to be shown on a package or on an alternative document. However, the substances have to be transported to and from an airport so there is an issue of intermodal transport.

Among the commenters, there was, perhaps, some agreement on changing the shipping name for UN3373 to "Category B, Infectious substances".

Therefore, the proposal is to change the note following 2.6.3.2.2.2, the Dangerous Goods List and the alphabetical listing from "DIAGNOSTIC SPECIMENS or CLINICAL SPECIMENS" to "CATEGORY B, INFECTIOUS SUBSTANCE".

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