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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

Thirty-third session
Geneva, 30 June-9 July (a.m) 2008
Item 4 of the provisional agenda

LISTING, CLASSIFICATION AND PACKING

Ethylene Oxide (UN1040) Sterilization Units

Transmitted by the expert from the United Kingdom*

Introduction

1. The expert from the United Kingdom introduced informal document UN/SCETDG/32/INF14 during the thirty-second session of the Sub-Committee in order to gather the initial views of the Sub-Committee in respect of introducing a new special provision for the transport of ethylene oxide in glass ampoules. Following comments received during debate, a revised formal proposal is now being submitted for consideration.

2. Small quantities of ethylene oxide (less than 30 ml) in glass ampoules are used in special apparatus for the sterilization of medical instruments in clinics and surgeries. These small glass

* In accordance with the programme of work of the Sub-Committee for 2007-2008 approved by the Committee at its third session (refer to ST/SG/AC.10/C.3/60, para. 100 and ST/SG/AC.10/C.3/34, para.14) (routine listing and classification).

ampoules are placed in the apparatus together with the items to be sterilized. On activation, the ampoules are broken, releasing the gas that itself carries out the sterilisation process. (*Note: the Proper Shipping Name for UN 1040 includes ethylene oxide with nitrogen. It is not the intent of this proposal to apply the proposed Special Provision to any substance other than ethylene oxide*).

3. Ethylene oxide is a toxic and flammable gas and there are no limited or excepted quantity provisions for the transport of this substance. Packing Instruction P 200 does recognise that this gas can be carried in glass ampoules (special packing provision "I") but this provision requires a UN tested package marked, labelled and documented in accordance with Part 5 of the Model Regulations. These small packages are usually sent to small, local clinics and surgeries and need to be easily transported through the small parcel distribution systems which rely on distributors being able to utilise limited and excepted quantity provisions. Such distribution appears to be carried out worldwide in thousands of separate consignments.

Background

4. Some ten years ago the ICAO Dangerous Goods Panel recognised this issue and adopted the following special provision:

"A131 Sterilization devices, when containing less than 30 ml per inner packaging with not more than 300 ml per outer packaging, may be transported on passenger and cargo aircraft in accordance with the provisions in 1;2.4, irrespective of 1;2.4.2.2 and the indication of "Forbidden" in columns 9 to 12 of the Dangerous Goods List (Table 3-1). In addition, after filling, each inner packaging must be determined to be leak-tight by placing the inner packaging in a hot water bath at a temperature, and for a period of time, sufficient to ensure that an internal pressure equal to the vapour pressure of ethylene oxide at 55 °C is achieved. Any inner packaging showing evidence of leakage, distortion or other defect under this test may not be transported under the terms of this special provision. In addition to the packaging required by 1;2.4, inner packagings must be placed in a sealed plastics bag compatible with ethylene oxide and capable of containing the contents in the event of breakage or leakage of the inner packaging. Glass inner packagings must be placed within a protective shield capable of preventing the glass from puncturing the plastics bag in the event of damage to the packaging (e.g. crushing)."

5. The leak-tightness determination specified is the same as that found in gas specific provision "I" in Packing Instruction P200. The protective shield referred to is usually provided by fibreboard tubes or other dividing partitions. A photograph of a typical example of the packaging currently used is attached to this document, see Annex. Obviously A131 applies only to air transport. At the moment it is therefore impossible for this substance to move by land or sea in the same manner, unless the journey is an international one involving an air transport leg, unless the competent authority is willing and able to issue an approval.

Proposal

6. Clearly these devices are now already moving around the world by land and sea. The expert from the United Kingdom believes there is no reason why a provision similar to A131 should not be adopted into the Model Regulations for UN 1040 allowing this substance to be moved multi-modally in the same way. In addition to editorial amendments necessary to address multi-modal provisions, it was clear from comments received by Sub-Committee members at the last session that the text developed for air transport can, and should, be substantively improved. Since the text is rather lengthy, we believe that the lay-out can also be improved to increase user-friendliness. The expert from the United Kingdom introduced his previous proposal on the basis of not deviating from the existing air transport text more than absolutely necessary. If the text now proposed below is adopted, clearly the ICAO Technical Instructions should consider amending its own text in the same way.

7. The expert from the United Kingdom now proposes the following new Special Provision to be assigned to the entry in the Dangerous Goods List for UN 1040 ethylene oxide:

“SPXXX Glass inner receptacles (such as ampoules or capsules) used in sterilization devices, when containing less than 30 ml of ethylene oxide per inner packaging with not more than 300 ml per outer packaging, may be transported in accordance with the provisions in Chapter 3.5, irrespective of the indication of E0 in column 7a of the Dangerous Goods List provided that:

- (a) After filling, each glass inner receptacle shall be determined to be leak-tight by placing the glass inner receptacle in a hot water bath at a temperature, and for a period of time, sufficient to ensure that an internal pressure equal to the vapour pressure of ethylene oxide at 55 °C is achieved. Any glass inner receptacle showing evidence of leakage, distortion or other defect under this test shall not be transported under the terms of this special provision; and
- (b) In addition to the packaging required by 3.5.2, each glass inner receptacle shall be placed in a sealed plastics bag compatible with ethylene oxide and capable of containing the contents in the event of breakage or leakage of the glass inner receptacle; and
- (c) Each glass inner receptacle shall be protected by dividing partitions or sleeves capable of preventing puncture of the plastics bag in the event of damage to the packaging (e.g. by crushing).”

Annex

Ethylene oxide

