UNITED NATIONS **ST**

Secretariat

Distr.
GENERAL

ST/SG/AC.10/C.3/2006/19
ST/SG/AC.10/C.4/2006/4
5 April 2006

Original: ENGLISH

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-ninth session
Geneva, 3-12 (a.m.) July 2006
Item 6 of the provisional agenda

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

Eleventh session
Geneva, 12 (p.m.)-14 July 2006
Item 4 (c) of the provisional agenda

LISTING, CLASSIFICATION AND PACKING

Classification criteria for Division 6.1 and Class 8 Human Experience

Transmitted by the expert from the United Kingdom

Introduction

1. The expert from the United Kingdom draws the attention of the Sub-Committee of Experts on the Transport of Dangerous Goods to the difficulties experienced by the enforcement authorities in the United Kingdom over the prosecution of a consignor of toxic material. These difficulties have highlighted apparent deficiencies in the classification criteria for substances in Division 6.1 and also Class 8.

   Note: This document is also submitted to the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals for information.

2. Paragraph 2.6.2.3 of the UN Model Regulations details the criteria for the classification of toxic substances and assignment to the applicable packing group. However, paragraph 2.6.2.2.2 indicates that the preferred route of classification is to base it on "human

experience in instances of accidental poisoning, and of special properties possessed by any individual substance such as liquid state, high volatility, any special likelihood of penetration, and special biological effects." It is not clear whether assessing human experience depends on positively researching numerous texts and medical references, or simply on knowledge already possessed by the person making the classification. Such information may be anecdotal in nature, and in the case of publications vary from edition to edition. If the mechanism for obtaining information is unclear, so is the required quality and reliability of that information. There is no indication of what information might be viewed as suitably authoritative or how much searching has to be undertaken.

3. If such information can be obtained, a person must then assign the substance to a packing group by making a judgment as to whether the toxicity risk is very severe, serious or relatively low (paragraph 2.6.2.2.1). However, what is "very severe" to one person may be "serious" to someone else i.e. the determination is subjective. By contrast, the grouping criteria in table 2.6.2.2.4.1 are value based but obtained from animal experiment data. As there are difficulties in the classification of these substances because many experiences cannot be exactly replicated, their frequent non-quantitative nature, and the difficulty with objective measurement, greater consistency could be achieved by requiring that any person classifying a substance records how he has reached his decision. This could aid in classifying future similar consignments, as well as providing an 'audit trail' in the event of subsequent problems with the consignment in question.

4. Human experience is also used in classifying substances of Class 8 and mixtures of gases exhibiting corrosive properties.

5. The Globally Harmonised System of Classification and Labelling of Chemicals (GHS) Chapter 1.3 Classification of Hazardous Substances and Mixtures gives greater guidance on the use of available data, test methods and test data quality.

6. In addition, the use of quantitative structure-activity relationships (QSARs) or surrogate data are often used as part of the expert judgement approach in classification of mixtures and articles when data for individual components are not available.

Proposal

7. The expert from the United Kingdom believes that inserting new text to reflect recommended practice in the GHS on current classification practices, especially for mixtures when data for individual components is not available, will help alleviate uncertainty in this area.

8. <u>The expert from the United Kingdom would welcome discussion by the Sub-Committee on this subject. Below is his suggested proposal for inclusion in the Model Regulations</u>

9. Insert the following new paragraphs after 2.6.2.2 for Class 6.1 and 2.8.2.4 for Class 8.

"1. In the case of human experience, reliable epidemiological data and experience of the effects of chemicals on humans (e.g. occupational data, data from accident databases) shall be taken into account in the evaluation of human health hazards of a chemical.

2. Competence on the part of the classification authority shall be required in interpreting data for hazard and packing group classification of substances, especially where weight of evidence judgments are needed or the use of surrogate data.

3. The quality and consistency of the data are important. Positive effects which are consistent with the criteria for classification whether seen in humans or animals, will normally justify classification, See Note.

4. In the case of a substance where the above procedure has been followed a record shall be kept of the expert judgement and the data used. This record shall be maintained for at least one year after the substance was last carried.

Note: Where evidence is available from both sources and there is a conflict between the findings, the quality and reliability of the evidence from both sources must be assessed in order to resolve the question of classification. Generally, data of good quality and reliability in humans will have precedence over other data. Positive results from well-conducted animal studies are not necessarily negated by the lack of positive human experience but require an assessment of the robustness and quality of both the human and animal data. In some cases classification results may be based on data from previous tests results providing that the data meets the latest classification criteria. For others, classification of a substance or a mixture is made on the basis of the total weight of evidence. This means that all available information bearing on the determination of toxicity is considered together, including the results of valid *in vitro* tests, relevant animal data, and human experience such as epidemiological and clinical studies and well-documented case reports and observations".

_____