



**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****Forty-second session**

Geneva, 3 – 11 December 2012

Item 2 (b) of the provisional agenda

**Recommendations made by the Sub-Committee on its thirty-ninth,
fortieth and forty-first sessions and pending issues:
listing, classification and packing****Adoption of expert judgement and weight of evidence
procedures into the Model Regulations on the Transport of
Dangerous Goods****Transmitted by the European Chemical Industry Council (CEFIC)¹****Introduction**

1. This proposal was presented as informal document INF.28 by CEFIC at the forty-first session of the Sub-Committee in June/July 2012. The Sub-Committee noted that the text prepared was extracted from the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Some experts expressed support for the proposal, however most experts were reluctant to adopt such a text on the basis of an informal paper and the Chairman suggested that experts should discuss this issue with their counterparts in the GHS Sub-Committee. The issue was also mentioned in the note by the secretariat for the GHS meeting about the work of the TDG (see section 9 of informal document INF.31). CEFIC therefore submits its proposal now as a formal document for this session.

2. Whereas classification criteria based on tests are already harmonized, because the TDG and GHS sub-committees make both use of the same OECD test guidelines, discussions at the meeting of the joint TDG-GHS working group on corrosivity criteria in December 2011 (see informal document INF.28/Rev.1), revealed that for further

¹ In accordance with the programme of work of the Sub-Committee for 2011-2012 approved by the Committee at its fifth session (refer to ST/SG/AC.10/C.3/76, para. 116 and ST/SG/AC.10/38, para. 16).

harmonization the implementation of semi-quantitative and qualitative criteria is necessary. In this respect the concepts of “expert judgement” and “weight of evidence” are required for correctly interpreting data for classification purposes.

3. Therefore CEFIC proposes including the GHS text of subsections 1.3.2.4.7 and 1.3.2.4.8, preceded by an introductory text based on GHS subsection 1.3.2.1.2, into Chapter 2.0 of the Model Regulations. Regarding the most appropriate location of the new text within this chapter, CEFIC is looking for advice from the Sub-Committee.

Proposal

4. Add the following new text to Chapter 2.0:

2.0.x General considerations

2.0.x.1 One objective of the Model Regulations is for it to be simple and transparent with a clear distinction between classes and packing groups in order to allow for “self-classification” as far as possible. For many classes the criteria are semi-quantitative or qualitative and expert judgement is required to interpret the data for classification purposes.

2.0.x.1.1 Expert judgement

The approach to classifying mixtures includes the application of expert judgement in a number of areas in order to ensure existing information can be used for as many mixtures as possible to provide protection for human health and the environment. Expert judgement may also be required in interpreting data for hazard classification of substances, especially where weight of evidence determinations are needed.

2.0.x.1.2 Weight of evidence

2.0.x.1.2.1 For some hazard classes, classification results directly when the data satisfy the 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.

2.0.x.1.2.2 The quality and consistency of the data are important. Evaluation of substances or mixtures related to the material being classified should be included, as should site of action and mechanism or mode of action study results. Both positive and negative results are assembled together in a single weight of evidence determination.

2.0.x.1.2.3 Positive effects which are consistent with the criteria for classification in each chapter, whether seen in humans or animals, will normally justify classification. 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. However, even well- designed and conducted epidemiological studies may lack sufficient numbers of subjects to detect relatively rare but still significant effects, or to assess potentially confounding factors. 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 relative to the expected frequency of occurrence of effects and the impact of potentially confounding factors.

2.0.x.1.2.4 Route of exposure, mechanistic information and metabolism studies are pertinent to determining the relevance of an effect in humans. When such information raises doubts about relevance in humans, a lower classification may be warranted. When it is clear that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified.

2.0.x.1.2.5 Both positive and negative results are assembled together in the weight of evidence determination. However, a single positive result performed according to good scientific principles and with statistically and biologically significant positive results may justify classification.
