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 **7 June 2012**

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Item 3 (b) of the provisional agenda
Listing, classification and packing: miscellaneous

Adoption of expert judgement and weight of evidence procedures into the UN Model Regulations

Transmitted by the European Chemical Industry Council (CEFIC)

Introduction

1. Whereas classification criteria based on tests are already harmonized, because TDG and GHS 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 UN/SCEGHS/22/INF.28/Rev.1), revealed that for further 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.

2. 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 UN Model Regulations. Regarding the most appropriate location of the new text within this chapter, CEFIC is looking for advice from the Sub-Committee.

Proposal

Add the following new text to Chapter 2.0:

"2.0.x General considerations

2.0.x1 One objective of these 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.x1.1 ***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.x1.2 *Weight of evidence*

2.0.x1.2.1 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.x1.2.2 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.x1.2.3 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.x1.2.4 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.x1.2.5 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.”