

## 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 Globally Harmonized  
System of Classification and Labelling of Chemicals

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Item 3 (e) of the provisional agenda

**Classification criteria and related hazard communication:  
miscellaneous**

## **Revised terms of reference for the informal working group on the use of non-animal test methods for classification of health and environmental hazards**

**Transmitted by the experts from the Netherlands and the United  
Kingdom**

### **Background**

1. At the thirty-first session, the Sub-Committee gave the informal working group on non-animal test methods their terms of reference<sup>1</sup>. The group now propose to revise the terms of reference to enable the group to identify certain types of corrections or improvements during the review of the chapters to integrate non animal test methods, as detailed in paragraph (d) below.

### **Proposal**

2. The following terms of reference are proposed:
- (a) Using a step-wise approach, starting with a hazard class to be determined by the informal working group, identify and evaluate<sup>2</sup>, relative to existing accepted *in vivo* test methods upon which the existing GHS classification criteria are based:
    - (i) The available *in vitro* and *in chemico* test methods, validated at the international level (e.g., OECD, ICATM, etc.), that could be used for GHS hazard classification, for health hazard and environmental (i.e. aquatic toxicity) hazard classes, including their applicability domains, limitations (such as accuracy, sensitivity, specificity) and expected future developments.
    - (ii) The existing guidance on *in silico*, including grouping approaches, QSARs and read-across, that could be useful for GHS hazard classification for health hazard and environmental hazard classes, including their limitations, uncertainties and validation; and
  - (b) For each relevant GHS hazard class and category, assess:
    - (i) Where substances and mixtures may be classified using the results of non-animal methods taking into account all relevant scientific

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<sup>1</sup> see ST/SG/AC.10/C.4/62 and informal document INF.27/Rev 2 (31<sup>st</sup> session).

<sup>2</sup> It is not foreseen to have a complete evaluation of all existing guidance or to cover all new developments. The work by the informal working group should focus on relevant information in relation to the possible amendments or additions to GHS classification.

information; and whether new or amended GHS classification criteria are needed to facilitate the use of such methods for hazard classification, and

- (ii) whether an integrated or tiered evaluation approach taking into account all relevant scientific information and combination of methods for hazard classification should be developed.
  - (c) Prepare draft amendments and additions to the GHS to facilitate hazard classification using non-animal methods, where appropriate and considering relevant limitations and uncertainties. They should include as appropriate classification criteria, notes, decision logic, tiered evaluation and guidance, and should take into account the needs of all sectors. The proposed changes should provide, so far as possible, a consistent approach across the different hazard classes. If appropriate, suggestions for further developments of non-animal methods should be given.
  - (d) To identify technical errors and/or editorial improvements during the review of chapters that are not related to non-animal criteria and send them to the appropriate workgroup (e.g. PCI) for implementation or present them in a working paper directly to the Sub-Committee.
  - (e) Report progress to the GHS Sub-Committee as appropriate.
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