

## 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

7 July 2016

### Thirty-first session

Geneva, 5– 8 July 2016

Item 3 (f) of the provisional agenda

Classification criteria and related hazard communication:  
miscellaneous

### Comments on the terms of reference in ST/SG/AC.10/C.4/2016/7

Transmitted by the expert from the United States of America

#### Background

1. The United States of America thanks the representative from the Netherlands and the United Kingdom for developing the paper ST/SG/AC.10/C.4/2016/7 which proposes the establishment of a GHS informal working group as the most appropriate way forward in promoting the replacement of animal testing with non-testing approaches (*in vitro* and *in chemico* test methods) for hazard classification, and the establishment of a GHS informal working group on promoting such work in a stepwise approach.

#### Comments

2. However, after additional review of the proposed terms of reference, the United States believes that the identification and evaluation of existing grouping approaches should be expanded to all hazard classes (e.g., human, environmental).

3. In addition, the United States believes the terms of reference should be further defined to clarify the level of international effort involved for validation (e.g., whether validated at the OECD, or validated in a member country.).

4. Further, the United States encourages flexibility in assessing hazard classification approaches with this proposed work plan. If an *in vitro*, or *in chemico* or grouping approach lacks robustness in classifying a hazard, an integrated approach may fill that need. The terms of reference should include and consider alternative approaches, including *in silico* methods, where those approaches may fit into the GHS.

#### Proposal

5. In the attached appendix, the United States presents proposed revisions to the terms of reference as suggested above.

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Deleted: 5. The United States is also concerned about how these approaches will be applied in practise. That is, some methods may require computer modelling. Although regulatory agencies in some implementing countries may have the resources to perform such modelling, such resources may not be available to those implementing countries where classification is conducted by industry.

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## Appendix

### Proposal

6. The experts from the Netherlands and the United Kingdom consider the most appropriate way forward to be the establishment of a GHS informal working group on promoting the use of non-animal test methods in GHS classification. The working group would work in a step-wise fashion, taking into account that a “one-size-fits-all” approach may not be appropriate for all hazard classes. In taking forward its work, the informal working group may wish to establish sub-groups on read across and on *in vitro*/*in chemico*/*in silico* approaches.

7. 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>21</sup>, relative to existing accepted *in vivo* test methods:

- (i) The existing guidance on grouping approaches that could be useful for GHS hazard classification for health hazard and environmental (i.e., aquatic toxicity) hazard classes, including their limitations and uncertainties; and
- (ii) The available *in vitro*, *in silico* 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 hazard classes, including their applicability domains, limitations (such as accuracy, sensitivity, specificity) and expected future developments.

(b) For each relevant GHS hazard class and category, assess:

- (i) Where substances and mixtures may be classified using grouping approaches, taking into account all relevant scientific information; and whether new or amended GHS classification criteria are needed to facilitate the use of such methods for hazard classification, and
- (ii) Where the results of validated *in vitro*, *in silico* or *in chemico* test methods can be used directly for hazard classification of substances and mixtures, and whether new or amended GHS classification criteria are needed to facilitate the use of such methods, or combinations of methods, whether in an integrated or tiered evaluation approach for hazard classification.

(c) Prepare draft amendments and additions to the GHS to facilitate hazard classification using grouping and *in vitro*, *in silico* or *in chemico* approaches, 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 read across and *in vitro*, *in silico* or *in chemico* approaches should be given.

<sup>21</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 the possible amendments or additions to GHS classification.

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**Moved down [1]:** The proposed changes should provide, so far as possible, a consistent approach across the different hazard classes.

**Moved down [2]:** If appropriate, suggestions for further developments of read across and *in vitro*, *in silico* or *in chemico* approaches should be given.

**Moved (insertion) [1]**

**Moved (insertion) [2]**

(d) Report progress to the GHS Sub-Committee as appropriate.

8. The Sub-committee is invited to agree on the terms of reference in paragraph 7 above for the informal working group on promoting the use of non-animal test methods in GHS classification.

**Deleted:** In taking forward its work the informal working group may wish to establish sub-groups on read across and on *in vitro/in chemico/in silico* approaches. The informal working group may also want to take a stepwise approach, starting with selected hazard classes and categories.