

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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Use of non-animal testing methods for classification of health hazards

Use of non-animal testing methods for classification of health hazards: Status report and proposed continuance of work

**Transmitted by the experts from the United Kingdom and the
Netherlands on behalf of the informal correspondence group**

Introduction

1. This informal paper provides an update on the work performed by the correspondence group on “Use of non-animal testing methods for classification of health hazards” since the thirty-third session of the Sub-Committee.

Background

2. The Sub-Committee agreed to keep the work on the use of non-animal testing methods for classification of health hazards on its programme of work for the 2017-2018 biennium (see ST/SG/AC.10/C.4/64). Information on the mandate/terms of reference of the correspondence group is in INF.27/Rev.2 (thirty-first session) and the report of the Sub-Committee on its thirty-first session (ST/SG/AC.10/C.4/62 paragraph 26).

3. Since the last meeting of the Sub-Committee, the correspondence group held teleconferences on 12 September, 26 September, and 6 November 2017. There has been a good level of participation and much interest in this work.

Status report

4. At the thirty-third session of the Sub-Committee an oral update of the progress of the informal working group was presented. At that stage, the correspondence group had decided that the best starting point was the hazard class skin corrosion/irritation (Chapter 3.2. of GHS). Draft text proposals for chapter 3.2.2 on the criteria for classification of substances were discussed. However, no agreement on the level of details for the criteria for the in vitro methods was reached. Further, the use of a tiered approach or an integrated approach was discussed without reaching an agreement. A teleconference on this subject between a limited number of experts was planned on 12 September 2017.

5. At the teleconference of 12 September, it was identified that the differences between the tiered approach as currently applied within GHS for skin irritation/corrosion is limited and a number of issues were identified as well as possible ways to resolve the issues.

6. At the teleconference of 26 September, the level of detail for the criteria for in vitro tests was discussed but not resolved. Still three options (no detailed criteria, full detail criteria or a table as guidance) are available. Further, additional issues on the use of a tiered or integrated approach were identified for further discussion.

7. At the teleconference of 6 November of a limited number of experts, the strengths and shortcomings of the tiered and integrated approach were discussed and written comments were requested. The written comments provided by Germany were adapted and provided to the correspondence group for further discussion in December in Geneva. A number of practical issues related to the tiered or integrated approach were accepted without much discussion namely: the acceptance of a negative in vitro test for concluding no classification for member states not applying category 3 and the need for additional information to discriminate category 3 from no classification for those member states applying category 3. The weight or the place in a tiered approach of acute dermal tests versus in vitro tests was discussed but no agreement reached. A proposal from the US to incorporate more elements such as weight-of-evidence of an integrated approach into the tiered approach was shortly discussed and written comments were requested.

6 December 2017 meeting

8. The correspondence group met on the morning of 6 December, and good progress was made on a number of issues regarding skin irritation and corrosion. The correspondence group agreed to limit the level of detail on the criteria for the in vitro methods but to include a detailed table in the guidance at the end of the chapter 3.2. Further, it was agreed that there are many commonalities between the OECD integrated approach, the current GHS tiered approach and the ECHA CLP guidance. This led to agreement to integrate more weight of evidence into the GHS tiered approach using as a starting point the ECHA tiered approach. A paper on human test results and how they can be used for classification within an overall weight-of-evidence assessment was discussed. Some experts considered this to be outside the scope of the work of the group. However, some participants that presently make use of human data to classify for skin corrosion and irritation agreed to find out more about how classifications were derived in practice from patch tests and other human data. The correspondence group also agreed that certain negative in vitro tests can be accepted for concluding no classification for jurisdictions not adopting category 3, and the need for additional information to discriminate category 3 from no classification for those jurisdictions adopting this category.

9. The correspondence group on skin irritation and corrosion will continue its work by a teleconference at the end of February and is asking for written comments on the issues not yet finalised by mid-January. The preparatory work on eye irritation and skin sensitisation has started and will expand in 2018. This will give the group a wider perspective as it continues its detailed work preparing proposed amendments to the text of Chapter 3.2 of the GHS in accordance within its terms of reference.