

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

12 June 2017

Thirty-third session

Geneva, 10-12 July 2017

Item 2 (d) of the provisional agenda

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-second 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 31 January, 16 February and 12 April 2017. There has been a good level of participation and much interest in this work.

Status report

4. At the thirty-second 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). Relevant available documents and guidelines on skin irritation were gathered and discussed by a sub-group of experts.

5. As preparation for the teleconference on 31 January 2017, experts from the Netherlands prepared three documents on possible approaches to adapt Chapter 3.2 to provide more detail on classification using *in vitro* and *in silico* methods, and weight of evidence approaches. Participants considered:

- For *in vitro* methods: whether to include a specific sub-chapter “Classification based on standard *in vitro* test data” between section 3.2.2.1 “Classification based on standard animal test data” and section 3.2.2.2 “Classification in a tiered approach”. Additionally whether to include a full description of the criteria.
- For *in silico* methods: whether to include a specific section “Classification based on *in silico* methods” after the *in vivo* and the *in vitro* sections, providing a short text that can be used for all or most hazard classes. A general section on *in silico* methods may be included in the general part of the GHS, for example a new section 1.3.2.4.10 “*In silico* methods”.
- For weight of evidence: whether to use an integrated approach to testing and assessment, including weight of evidence in line with OECD Guidance Document 203 instead of a tiered approach.

6. As there were a range of views on the level of detail that should be included on *in vitro* methods, experts from the Netherlands prepared three text options with different levels of details:

- (a) Minimal *in vitro* criteria;
- (b) Full *in vitro* criteria, and
- (c) Full *in vitro* criteria with additional details (e.g. applicability domain).

These three text proposals were discussed during the teleconference on 12 April 2017. Option (c) was not supported; discussion continues on options (a) and (b).

7. Good progress is being made by the correspondence group in identifying and evaluating the available *in vitro* and *in chemico* methods and the available guidance on *in silico* and other grouping approaches for skin corrosion/irritation, and in determining where substances and mixtures may be classified using the results of non-animal methods. The outcome of this work for skin corrosion/irritation will provide a good model for future work to adapt the text of other GHS health hazard classes to facilitate hazard classification using non-animal methods.

11 July 2017 meeting

8. The correspondence group will continue its discussions on the use of non-animal testing methods in GHS at a face-to-face meeting on 11 July. Experts from the Netherlands and the United Kingdom will present new text proposals for Chapter 3.2 integrating the comments from correspondence group members. The Sub-Committee will receive feedback on progress. As always, Sub-Committee members are invited to participate in the meeting, which will be held in Room S4 (Moroccan room), on the 3rd floor of the Palais des Nations from 12:45-14:15.
