

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**

29 November 2019

Thirty-eight session

Geneva, 11-13 December 2019

Item 2 (c) 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

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

Introduction

1. This informal paper provides an update on the work performed by the Working Group on “Use of non-animal testing methods for classification of health hazards” since the thirty-seventh 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 2019-2020 biennium (see ST/SG/AC.10/C.4/72). Information on the mandate/terms of reference of the correspondence group is in informal document INF.27/Rev.2 (31st session) and the report of the Sub-Committee on its thirty-first session (ST/SG/AC.10/C.4/62 paragraph 26).

3. The Sub-Committee agreed with the proposal of the informal working group to review and revise either Chapter 3.3 on serious eye damage and eye irritation, or Chapter 3.4 on skin sensitisation in 2019/2020. As part of the review of Chapter 3.3, the informal working group will consider again the specific issue of classification using pH to resolve, in particular, the current ambiguity on whether the appropriate classification is corrosive or inconclusive where a substance or mixture has extreme pH and low acid/alkaline reserve.

4. The Working Group presently has approximately 50 members, reflecting the importance of, and interest in, this work. Its membership includes experts with specialised knowledge of test methods and their application to classification, and experts on national legislation that implements GHS. Discussions are often lively and detailed, but overall are propelled by a strong desire to make progress on the informal working group’s mandate and ensure that non-animal test methods are consistently incorporated in the GHS in a way that reflects their growing importance and scientific relevance, whilst recognising their limitations.

Status report

5. It was agreed at the webex meeting in February 2019 that the informal working group will start their work in 2019/2020 on serious eye damage/eye irritation, alongside continuing its consideration of the pH rule. See informal document INF.17 (37th session) for additional information.

6. The European Commission's Joint Research Centre (JRC) prepared an issue paper on serious eye damage/eye irritation, which states that the update will be in line with the update of chapter 3.2 on skin irritation/corrosion and included points for discussion that are specifically relevant to Chapter 3.3. The purpose of the paper was to discuss the issues and where possible to reach consensus before starting the revision of Chapter 3.3. The document was discussed in a webex meeting on 11 June 2019 and at a face-to-face meeting on 9 July 2019. During the face to face meeting, it was agreed by the informal working group that the work would be continued by starting to draft a revision of Chapter 3.3.

7. In September, a first draft of Chapter 3.3 was created by JRC. The document was discussed with United Kingdom and the Netherlands and after minor revision it was sent to the Working Group for comments. This first revision was discussed during the webex meeting on 7 November 2019. The main discussions were on the paragraphs on in vitro/ex vivo data, the tiered approach including Figure 3.3.1, and the background guidance on the use of human data.

8. Based on the outcome of the discussions, the draft Chapter 3.3 will be further revised and discussed again at the face to face meeting on 11 December in Geneva. In addition, the application of a weight of evidence analysis and examples of classification will be discussed to continue the work on how to assess the outcome of in vitro/ex vivo studies.

9. The discussion on classification using pH has continued in this biennium based on a thought starter document prepared by Netherlands. The document indicated the different interpretations of the GHS text and referred to existing guidance documents of the EU, OSHA and OECD. Further, it provided an overview of the discussions and suggestions for a way forward.

10. The thought starter was discussed with the group at the webex meeting in February. It was considered useful to review existing data to reassess the confidence of classifying on the basis of pH, with or without acid/alkali reserve. Initiatives for collecting and analysing data are ongoing.

On-going work

11. The informal working group on non-animal test methods will continue its work at its face-to-face meeting on 11 December 2019 (for the agenda see Annex I) and subsequent teleconferences as necessary.

Annex

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**

11 December 2019, 13:00 – 14:30 CET

Informal working group on use of non-animal testing methods for the classification of health hazards

Room IV

Agenda: informal working group on non-animal test methods

- 1) Welcome and introduction
- 2) Summary notes of the webex meeting at 7 November 2019 (document 1)
- 3) Discussion of draft revision of Chapter 3.3 (document 2)
- 4) Examples classification (document 3)

Documents for discussion:

- 1 GHS WG non-animal testing - draft summary note face-to-face meeting – 7 November 2019_document 1
 - 2 Draft Chapter 3.3 Serious eye damage/eye irritation_GHS non-animal test methods – 11 December 2019_document 2
 - 3 Application of a WoE evaluation for classification for eye effects based on in vitro methods_document 3
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