

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**

2 July 2019

Thirty-seventh session

Geneva, 8-10 July 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-fourth 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 (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. The Sub-Committee agreed with the proposal of the 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 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 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. Since the last meeting of the Sub-committee in December 2018, the Working Group has convened twice by Webex (on 19 February and 11 June 2019). After each meeting the joint leads, the Netherlands and the United Kingdom, drafted minutes of the meeting and initiated actions based on comments and suggestions provided by the participants.

6. The discussion on classification using pH has continued based on a thought starter document prepared by NL. 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.

7. 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. Further, the group could explore policy options for classification when the only available information is pH and buffer capacity.

8. The next GHS hazard class chapter to be adapted in the new biennium, based on in vitro and in silico methods, was discussed at the working group meeting in Geneva in December 2018 but no conclusion was reached. Two hazard classes were considered: Chapter 3.3 on serious eye damage / eye irritation and Chapter 3.4 on skin sensitisation.

9. The NL and UK prepared an overview of the ongoing activities on both hazard classes and potential difficulties, which was discussed at the webex meeting in February 2019. There was agreement that there was still work to be completed within OECD in developing the defined approaches for skin sensitisation. Having the agreed OECD defined approaches was considered to be essential before the Working Group could start its work on skin sensitisation. For serious eye damage / eye irritation the available in vitro and ex vivo methods can already be used for classification, although with limitations. It was agreed that the Working Group will start their work on serious eye damage / eye irritation, alongside continuing its consideration of the pH rule.

10. 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 points for discussion are: 1) Limitations on the use of in vitro/ ex vivo data to classify Category 2; 2) Inclusion of validated but not yet OECD accepted in vitro/ ex vivo methods in the list of currently available guideline tests; 3) Capacity of in vitro/ ex vivo methods to identify discoloration of the cornea and effects on the iris; 4) Availability, relevance and use of human data and other animal data; and 5) Revisions to the tiered approach.

11. The purpose of the paper was to discuss these issues and where possible to reach consensus before starting the revision of Chapter 3.3. This paper was discussed by JRC, UK and NL and modified based on the discussions prior to being discussed by the Working Group during the webex meeting in June 2019. No consensus was reached. The paper will be updated and discussions will be continued.

On-going work

12. The Working Group on non-animal test methods will continue its work at its face-to-face meeting on 9 July (for the agenda see Annex I) and subsequent teleconferences as necessary.

Annex I

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**

9 July 2019, 17:30 – 19:00 CET

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

Room XII

Agenda: Working Group on Non-animal test methods

- 1) Welcome and introduction
- 2) Summary notes of the webex meeting at 11 June 2019 (document 1)
- 3) JRC issue paper on serious eye damage / eye irritation (document 2 and 3)

Documents for discussion:

- 1 GHS WG non-animal testing - draft summary note webinar discussion - 11 June 2019 document 1
 - 2 Issue paper CHAPTER 3.3_in vitro criteria introduction 11062019 document 2
 - 3 Example of classification based on in vitro methods document 3
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