

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**

01 December 2021

Fortieth session

Geneva, 8-10 December 2021

Item 2 (c) of the provisional agenda

Work on the Globally Harmonized System (GHS):

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 document provides an update on the work performed by the Informal Working Group on “Use of non-animal testing methods for classification of health hazards” since the last update provided to the Sub-Committee at the fortieth session in July 2021.

Background

2. At the thirty-ninth session, the Sub-Committee agreed to keep the work on the use of non-animal testing methods for classification of health and environmental hazard classes on its programme of work for the 2021-2022 biennium and agreed with the proposal for the group to continue the review of Chapter 3.3 on serious eye damage/eye irritation followed by commencing their work on Chapter 3.4 in relation to skin sensitization¹. Formal proposals to amend Chapter 3.3², together with the related consequential amendments to Chapters 1.2 and 3.2³, were adopted at the fortieth session⁴ in July 2021.

3. The informal working group presently has approximately 60 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

4. Since the last update to the GHS Sub-Committee in July 2021, the informal working group has continued to work hard on the revision of Chapter 3.4 for skin sensitization for the

¹ see ST/SG/AC.10/C.4/78

² see ST/SG/AC.10/C.4/2021/4 and informal documents INF.3 and INF.22 (40th session)

³ see ST/SG/AC.10/C.4/2021/5 and informal document INF.4 (40th session)

⁴ see ST/SG/AC.10/C.4/80

inclusion of non-animal testing methods at three virtual meetings (9 September 2021; 21 October 2021; and 30 November 2021).

5. At the September meeting, the group continued the discussions on the Chapter 3.4 scoping document, and further developed the list of issues to be resolved on the skin sensitization hazard class.

6. During the October virtual meeting, the group commenced the discussions on the first draft of a schematic on classification criteria for the skin sensitization hazard class to include non-animal testing methods.

7. In addition, members from Germany presented a paper on the correctness of the sequence defined in paragraph 1.3.2.3.1, concerning the use of concentrations limits versus test results with the whole mixture, for mixtures to be classified for skin sensitisation, posing several questions including, if the issue is deemed relevant by the IWG members and that future work on this topic would have value and deserve further exploration, and, if so, whether the issue should be addressed by this group or another working group. Although there was no definitive view on how to proceed with this issue and written responses to the questions were requested, some members expressed that there may be wider implications for other chapters in the GHS and as such might be beyond the scope of this working group.

8. At the October meeting, the group also received feedback from the OECD webinar on the 'Implementation of Defined Approaches on skin sensitisation' that had been held on the 18 October 2021, that had followed the publication of the related OECD Guideline 497⁵ in June 2021. Three members of the informal working group had provided presentations at the OECD webinar, while other members of the group who had also attended expressed how informative and relevant it was to the current work of the group.

On-going work

9. The work on reviewing the skin sensitization hazard class in Chapter 3.4 for the inclusion of non-animal testing methods is continuing at pace with the aim of providing a formal proposal on the revised Chapter 3.4 in 2022.

10. At the November 2021 meeting, further discussions are planned on the next version of the draft schematic for Chapter 3.4 and on the initial draft of several revised sections of Chapter 3.4. In addition, a brief update will be provided on the responses to the questions in the German paper, together with further consideration of how this issue should be progressed.

11. The Sub-Committee is invited to note the progress of the revision of Chapter 3.4 for the skin sensitization hazard class as provided in this informal document and is also invited to provide views on whether technical issues with wider implications for other chapters in the GHS should be considered by an alternative working group.

⁵ OECD Guideline No. 497: Defined Approaches on Skin Sensitisation