

## 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

16 November 2020

### Thirty-ninth session

Geneva, 9-11 December 2020

Item 8 of the provisional agenda

Programme of work for the biennium 2021-2022

## Preparation of the work programme for the biennium 2021- 2022 – Continuation of work on non-animal testing

**Transmitted by the experts from the Netherlands and the United  
Kingdom on behalf of the informal working group on the use of non-  
animal test methods for classification of health and environmental  
hazards**

### Background

1. The terms of reference the Sub-Committee gave to the informal working group on non-animal test methods (informal document INF.27/Rev.2, 31<sup>st</sup> session)<sup>1</sup> set out four main activities:

- (a) To identify and evaluate the available *in vitro* and *in chemico* test methods, validated at the international level, and the existing guidance on *in silico* methods, including grouping approaches, quantitative structure activity relationship (QSARs) and read-across, that could be useful for GHS hazard classification for health hazard and environmental hazard classes, using a step-wise approach, starting with a hazard class to be determined by the Group;
- (b) To assess for each hazard class whether an integrated or tiered evaluation approach should be developed, taking into account all relevant scientific information and combination of methods for hazard classification, and where substances and mixtures may be classified using non-animal methods, whether new or amended GHS classification criteria are needed;
- (c) To prepare draft amendments and additions to the GHS to facilitate hazard classification using non-animal methods where appropriate, taking into account relevant limitations and uncertainties. The amendments and additions should include as appropriate classification criteria, notes, decision logics, tiered evaluation and guidance, and should take into account the needs of all sectors;
- (d) To report progress to the GHS Sub-Committee as appropriate.

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<sup>1</sup> see ST/SG/AC.10/C.4/62 and informal document INF.27/Rev.2 (31<sup>st</sup> session).

2. In addition, at the December 2020 Sub-Committee meeting the informal working group also submitted a proposal to amend the terms of reference<sup>2</sup>. This proposal would enable the group to identify certain types of technical corrections and/or editorial improvements that are not related to non-animal criteria during the informal working groups review of the chapters to integrate non animal test methods. These corrections and/or improvements would then be sent to the appropriate workgroup (e.g. PCI) for implementation or presented directly to the Sub-Committee for consideration. Details of the proposed amendment to these terms of reference are provided in paragraph 2 (d) of informal document INF.26 (39th session).

3. The informal working group has around 60 members, reflecting the interest in its work. The latest status updates are informal documents INF.12 and INF.12/Rev.1 (39th session).

4. During the current biennium the informal working group has worked almost exclusively on revising Chapter 3.3 of the GHS and resolving the pH issue, as detailed in the groups 2019-2020 work plan<sup>3</sup>. Although the revision of Chapter 3.3 has not been completed this biennium, the group continues to work very hard towards this goal and hope to present a formal proposal on Chapter 3.3 to the Sub-Committee for consideration at its July 2021 meeting.

## Proposal

5. If the Sub-Committee is generally content with its approach, the informal working group proposes to continue working in a stepwise manner and build on the work undertaken so far.

6. Taking into account the general state of developments in non-animal testing methods and approaches, the working group proposes to address the following specific workstreams in 2021 – 2022 within its terms of reference (as summarised in paragraphs 1 and 2 above):

- **Workstream 1:** To continue to review and revise Chapter 3.3, Serious Eye Damage, Eye Irritation, following as appropriate the work already done on Chapter 3.2.
- **Workstream 2:** To review and revise Chapter 3.4 in regard to skin sensitisation.
- **Workstream 3:** To consider whether updates are needed in chapters 3.2 and 1.3 as a result of the group's work on chapters 3.3 and 3.4.

7. The Sub-Committee is invited to agree the work programme for 2021 - 2022 proposed in paragraph 6 above for the informal working group on non-animal testing.

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<sup>2</sup> see informal document INF.26 (39<sup>th</sup> session)

<sup>3</sup> see ST/SG/AC.10/C.4/72 and informal document INF.27/Rev.1 (36<sup>th</sup> session).