

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

21 November 2022

Forty-third session

Geneva, 7-9 December 2022

Item 7 of the provisional agenda

Programme of work for the biennium 2023-2024

Preparation of the work programme for the 2023-2024 biennium: 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 hazards

Background

1. The terms of reference the Sub-Committee gave to the informal working group on non-animal test methods that were revised at the thirty-ninth session¹ and set out five main activities, summarized as follows:

- (a) Using a step-wise approach, starting with a hazard class to be determined by the informal working group, identify and evaluate², relative to existing accepted *in vivo* test methods upon which the existing GHS classification criteria are based:
 - (i) The available *in vitro* and *in chemico* test methods, validated at the international level, that could be used for GHS hazard classification, for health hazard and environmental hazard classes.
 - (ii) The existing guidance on *in silico*, including grouping approaches, QSARs and read-across, that could be useful for GHS hazard classification for health hazard and environmental hazard classes; and
- (b) For each relevant GHS hazard class and category, assess:
 - (i) Where substances and mixtures may be classified using the results of non-animal methods taking into account all relevant scientific information; and whether new or amended GHS classification criteria are needed to facilitate the use of such methods for hazard classification, and
 - (ii) whether an integrated or tiered evaluation approach taking into account all relevant scientific information and combination of methods for hazard classification should be developed.

¹ See ST/SG/AC.10/C.4/78 and informal document INF.26 (thirty-ninth session).

² It is not foreseen to have a complete evaluation of all existing guidance or to cover all new developments. The work by the informal working group should focus on relevant information in relation to the possible amendments or additions to GHS classification.

- (c) Prepare draft amendments and additions to the GHS to facilitate hazard classification using non-animal methods which should, so far as possible, provide a consistent approach across the different hazard classes.
 - (d) To identify technical errors and/or editorial improvements during the review of chapters that are not related to non-animal criteria and send them to the appropriate informal working group (e.g. the practical classification issues (PCI) informal working group) for implementation or present them in a working paper directly to the Sub-Committee.
 - (e) Report progress to the GHS Sub-Committee as appropriate.
2. The informal working group has around 60 members, reflecting the interest in its work. The latest status update is provided in informal document INF.13 at this session.
3. During the current biennium the informal working group has worked hard to complete the revision of Chapter 3.3 of the GHS which was adopted at the fortieth session³, as detailed in the group's 2021-2022 work plan⁴. Although the revision of Chapter 3.4 for skin sensitization has not been completed this biennium, proposals in relation to the skin sensitization substance sections within the chapter are provided for the consideration of the Sub-Committee at this session. Further, the group continues to work very hard towards completing the revision of Chapter 3.4 and intends to present a formal proposal in relation to the skin sensitization mixtures sections within the chapter for the consideration of the Sub-Committee at its July 2023 meeting.

Proposal

4. 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.
5. 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 2023-2024 within its terms of reference (as summarised in paragraph 1 above):
- **Workstream 1:** To continue to review and revise Chapter 3.4, for skin sensitisation in relation to mixtures, following as appropriate the work already done on chapters 3.2 and 3.3.
 - **Workstream 2:** To review and, when possible, revise Chapter 3.4 for respiratory sensitisation. Identify and revise a different hazard class if revision of Chapter 3.4 for respiratory sensitisation is not possible.
 - **Workstream 3:** To consider whether updates are needed in chapters 1.3, 3.2 and 3.3 as a result of the group's work on Chapter 3.4.
6. The Sub-Committee is invited to agree the work programme for 2023 - 2024 proposed in paragraph 5 above for the informal working group on non-animal testing.

³ see ST/SG/AC.10/C4/80, ST/SG/AC.10/C4/2021/4; and informal document INF.3 (fortieth session).

⁴ see ST/SG/AC.10/C.4/78 and informal document INF.27 (thirty-ninth session).