

## 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

22 November 2024

Forty-seventh session

Geneva, 4-6 December 2024

Item 5 of the provisional agenda

Programme of work for 2025-2026

### Proposed work programme on non-animal methods for 2025-2026

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

### Background

1. The terms of reference for the informal working group on non-animal testing methods, as revised and agreed to by the Sub-Committee at the thirty-ninth session<sup>1</sup> set out five main activities, summarized below:

- (a) Using a stepwise approach, starting with a hazard class to be determined by the informal working group, identify and evaluate<sup>2</sup>, 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, quantitative structure-activity relationships (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

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

<sup>2</sup> 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.

- (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.
  - (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) 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 importance of, and interest in its work. The latest status update is provided in informal document INF.23 at this session.
3. During the current biennium the informal working group finalized the revision of chapter 3.4 in relation to the classification of skin sensitization for mixtures as detailed in the group's 2023-2024 work plan<sup>3</sup> and submitted a proposal that was adopted by the Sub-Committee at its forty-sixth session<sup>4</sup>. The agreed amendments to chapter 3.4 provisionally adopted by the Sub-Committee are included in the draft consolidated list of amendments in document ST/SG/AC.10/C.4/2024/11 for confirmation by the Sub-Committee at this session. In addition, following a request from the secretariat for an editorial review of the adopted text for paragraph 3.4.5.3.2.3.5, the informal working group agreed to the wording as proposed in informal document INF.7, for consideration by the Sub-Committee at this session.
4. Bearing in mind the scope of the work, the informal working group has also reflected on its name and considers that an amendment is needed to make it technically correct. This is because the scope of the work of the informal working group covers not only non-animal test methods but also non-test methods, some of which are already mentioned in the activities outlined in the terms of reference under paragraph 1 (a)(ii) above. The non-test methods that are used for non-animal classification for health and environmental hazards include: computer models predicting qualitative structure-activity relationships (structural alerts, SAR) or quantitative structure-activity relationships (QSARs), computer expert systems, and read-across using analogue and category approaches.
5. Therefore, for correctness and to better reflect the scope of the work undertaken by the group, it is proposed to amend the work item and the name of the informal working group by deleting the word 'testing', to read as shown in paragraph 7 below.

## Proposals

6. If the Sub-Committee is generally content with its approach, the informal working group proposes to work in a stepwise manner and, taking into account the general state of scientific developments in non-animal methods and approaches, to address the following specific workstreams in 2025-2026 within its terms of reference (as summarized in paragraph 1 above):

- Workstream 1: To review chapter 1.3 with regards to the possible addition of non-endpoint specific text on non-animal methods and carry out any

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<sup>3</sup> See ST/SG/AC.10/C.4/86 and informal document INF.16 (forty-third session).

<sup>4</sup> See ST/SG/AC.10/C.4/92 paragraph 20 and annex I.

consequential amendments in all health and environmental chapters, as required, to remove needless repetition.

- Workstream 2: To review the four paragraphs on non-testing methods imported from chapters 3.2, 3.3 and 3.4 into the draft version of chapter 3.5, as described in the annex to informal document INF.16 (forty-fifth session)<sup>5</sup>, discussing the rationale and background for their previous inclusion in these chapters to assess whether they can be edited/deleted in relation to concerns held by the germ cell mutagenicity informal working group.
- Workstream 3: To reassess which chapter has priority to be amended next. Possible options include an update of chapter 3.3 (Serious eye damage/irritation), chapter 3.1 (acute toxicity), or chapter 4.1 (Hazardous to the aquatic environment).

7. To rename the work item to read: **“Use of non-animal methods for classification of health and environmental hazards”** and to refer to the informal working group from now on as the “informal working group on the use of non-animal methods for classification of health and environmental hazards”.

## Action requested

8. The Sub-Committee is invited to agree to :
- (a) the proposed work programme for the informal working group for 2025–2026, as detailed in paragraph 6 above; and to
  - (b) the proposal to amend the name of the work item and the informal working group, as indicated in paragraph 7 above.

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<sup>5</sup> See informal document INF.16 (forty-fifth session).