

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

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Programme of work for the biennium 2021-2022

Review of the tiered approach for classification of mixtures

Transmitted by the expert from Germany

Background

1. In the course of the work of the Informal Working Group on Non-Animal Test methods (IWG NATM) over the last biennium, an inconsistency in the current version of the GHS between the classification strategies for mixtures and substances was identified.
2. The recommended process for classification of mixtures in paragraph 1.3.2.3.1 states that data on the mixture itself should always take precedence over data available for similar mixtures (“bridging”). Consequently, in chapters 3.2 and 3.3, information on the mixture which comes from lower tiers, such as extreme pH or (Q)SAR rules out reliable information available for similar mixtures.
3. In addition, read-across is used for substances within the tiered approaches, whereas for mixtures bridging is applied at a later stage. From a technical as well as scientific point of view, however, read-across and bridging are comparable in many ways. They both rely on the transfer of information from one substance or mixture to another. The only major difference is that over the last years, more elaborate and internationally accepted concepts have been developed for read-across (Ball et al., 2016; ECHA, 2017; Escher et al., 2019; Rovida et al., 2020)¹, whereas bridging is less standardised and mostly performed according to conventions developed under individual legislations.
4. Since experience shows that relevant and reliable information on similar mixtures in many cases is available, e.g. for cleaning or plant protection products, a breakout group of the IWG NATM considered it valuable to discuss further at which stage in the tiered approach in Chapter 3.3 data from similar mixtures should be taken into account. There was sympathy to give high-quality information on similar mixtures, e.g. standard animal or *in vitro* studies, a higher priority in the evaluation process than is currently the case.
5. Overall, there was a common understanding in the IWG NATM that future work on this topic would have value and deserves further exploration. The more so, as it is expected that the issue will also be of high relevance for the planned work on Chapter 3.4

¹ References :

Ball N et al. (2016). DOI: 10.14573/altex.1601251; ECHA (2017). DOI: 10.2823/619212; Escher S et al. (2019). DOI: 10.1007/s00204-019-02591-7; Rovida C et al. (2020). DOI: 10.14573/altex.1912181.

“Sensitization”. However, considerations will be complex and need detailed in-depth discussion. It might also be necessary to define quality standards for data on similar mixtures to be used for “bridging”. In addition, care needs to be taken not to induce unwanted consequential changes on other chapters or the need to reclassify mixtures already classified.

6. In the sections below a work plan is proposed to address this issue and find an appropriate solution for chapters 3.2, 3.3, 3.4 as well as Chapter 1.3.

Proposal

7. The Sub-Committee is invited to consider the proposed terms of reference and related workstreams for inclusion in the programme of work for the next biennium. The Sub-Committee is also invited to decide which informal working group is deemed appropriate to address the issues raised below. Possible options include:

Option 1: the IWG NATM (as an additional workstream under its terms of reference, given its relationship with non-test methods)

Option 2: the PCI informal working group (as an additional workstream under its terms of reference, given the overarching nature of the proposal).

Proposed terms of reference

Develop and propose a scientifically sound procedure for the tiered approach for classification of mixtures in chapters 3.2 to 3.4 allowing use of the available data in the most appropriate possible way. A preliminary evaluation will be conducted:

- (a) including an analysis of the present strategies for all health hazards and aiming at identifying when and how bridging principles are best to be considered in the classification process;
- (b) defining which requirements need to apply to data from similar mixtures to be useful for bridging purposes;
- (c) exploring by comparison with the relevant sections of Chapter 1.3, to which extent improvements of the classification process for mixtures in chapters 3.2 to 3.4 are compatible with the rules in Chapter 1.3.

If deemed necessary, options for improvement will be identified and proposed.

The proposed workstreams are detailed below:

Workstream 1: Analysis of the status quo

- (a) Review the relevant sections in the chapters in Part 3 “Health hazards” of the GHS to identify and analyse the stepwise procedure in the approaches for mixture vs. substance classification in each chapter;
- (b) Identify the current interlinkage between chapter-specific rules for mixture evaluation and the general rules as given in paragraph 1.3.2.3;

Workstream 2: Identify a procedure for the tiered approach for mixture classification in Chapters 3.2 to 3.4 which would allow to use the available data in the most appropriate way

- (a) Identify the quality standards for data from similar mixtures as a prerequisite to be used for bridging purposes;

- (b) Categorise the information as identified for the tiered approaches (substances) in chapters 3.2 to 3.4 with respect to the value of the information for the classification process of mixtures. With this categorisation a decision should be made, how to rank data on the mixture itself and similar mixtures according to their relevance and reliability for classification. Reference could be made to read-across for substances;
- (c) Based on the results from workstreams 2 (a) and 2 (b) develop an according workflow for the classification of mixtures for chapters 3.2, 3.3 and 3.4, either as a unified workflow (including tiered approaches and decision logics) for substances and mixtures or, if that is found inappropriate, as a revised separate workflow for mixtures.

Workstream 3: Explore the relevant sections in Chapter 1.3 with reference to the results of workstream 2 and propose additional or modifying text, if deemed necessary

- (a) Compare the results of workstreams 2 and 1 and identify possible inconsistencies or ambiguities concerning the procedures and the linkage of data for the respective chapters;
 - (b) Identify options to modify the text of Chapter 1.3 and chapters 3.2 to 3.4 to include the results from the analysis under 3 (a). and propose options for according development of chapters 3.2 to 3.4;
 - (c) Identify the need for consequential amendments on editorial or technical level and propose the according text, if deemed necessary;
 - (d) Use the results from workstreams 3 (a) and 1 (a) to identify whether also in chapters other than 3.2, 3.3, 3.4 inconsistencies between general rules and chapter-specific rules need to be considered. Propose, if necessary and appropriate, a work stream for the next working program of the Sub-Committee to reduce these inconsistencies in other chapters.
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