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 **30 June 2023**

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Item 2 (d) of the provisional agenda
Work on the Globally Harmonized System of Classification and Labelling of Chemicals: Classification criteria for germ cell mutagenicity

Status of the work of the informal working group on clarification of the criteria for classification for germ cell mutagenicity

Transmitted by the European Union on behalf of the informal working group on germ cell mutagenicity

Introduction

1. This informal paper provides an update on the work undertaken by the informal working group on clarification of the criteria for classification for germ cell mutagenicity since the forty-third session of the Sub-Committee.

Background

2. Reference is made to the proposal contained in ST/SG/AC.10/C.4/2020/13 and ST/SG/AC.10/C.4/2020/13/Add1, the informal document INF.37 (thirty-ninth session) (European Union) on the clarification of the criteria for classification for germ cell mutagenicity in category 1B and the report of the Sub-Committee on its thirty-ninth session (ST/SG/AC.10/C.4/78). Based on these documents the terms of reference and work programme of the informal working group on the criteria for classification for germ cell mutagenicity were submitted for discussion at the fortieth session (document ST/SG/AC.10/C.4/2021/3). The Sub-Committee adopted the terms of reference as amended by the informal document INF.24 transmitted by the expert of the United States of America as stated in the report of the fortieth session (ST/SG/AC.10/C.4/80). The informal working group reported on the progress of work at the forty-first (INF.14), forty-second (INF.15) and forty-third (INF.26) sessions. At the forty-third session the Sub-Committee agreed to carry-over the program of work of the informal working group work into the 2023-2024 biennium. The informal working group is aiming on finalisation of the revision of chapter 3.5 by the end of 2024.

Status report

3. As a follow-up to the forty-third session, the informal working group progressed the revisions and on-going discussions through written procedure and five online meetings. Points discussed and agreed are summarised in a living working document revised after each meeting. The informal working group agreed to consider revising the structure of chapter 3.5 to be aligned with the recently revised chapters 3.2, 3.3 and 3.4 where the criteria are provided for each type of data. In addition, the informal working group agreed to explore and discuss different options, i.e. maintaining, adapting or deleting the overarching criteria table, and to add some text on non-testing methods being consistent with chapters 3.2 to 3.4. However, discussions are ongoing on whether these paragraphs may need some adaptations.

4. Advice related to in vitro and non-testing methods will be requested from the informal working group on non-animal testing methods. The leads of the two groups have started to discuss how to best proceed.

5. Related to the discussion of the criteria of germ cell mutagenicity in category 1A, three options were considered. None of these options would have an impact on the number of currently classified substances nor on risk management and risk communication in most jurisdictions.

(a) The enlargement of the Category 1A, by moving criterion 1B(c) to 1A, as referring to human evidence. Although many of the members of the informal working group would agree to this option, other members raised objections to an enlargement of Category 1A, so no consensus was reached on this issue, yet.

(b) The possibility to merge Category 1A and 1B, and define common criteria for Category 1. This option may improve clarity in communication, as Category 1B classification may inappropriately be perceived as less critical than 1A, while also avoiding the necessity to agree on the correct sub-categorisation.

(c) Some members expressed a preference to maintain the current criterion for category 1A. In this case, it still will be necessary to clarify the text, as within the informal working group the current text leads to different interpretations.

However, having considered these options the informal working group at their last meeting agreed to address other issues in the chapter first and then revisit this discussion.

6. The informal working group already agreed to give at least equal weight to in vivo somatic and germ cell genotoxicity tests under Category 1B prior to the forty-third session. In addition, the group is considering whether to amend Category 1B to include evidence that a substance has reached the gonads as part of the criteria. The text of the Category 1B criteria has been reorganised in order to add a structure and clarity to the current text under 1B. However, due to the broader criteria discussion the final text is still to be agreed.

7. The Genetic Toxicology Technical Committee (GTTC) of the Health and Environmental Science Institute (HESI) informed the informal working group on the progress of their extended study investigating existing data on germ cell mutagenicity to, if possible, underpin the work of the informal working group to revise the current classification criteria. Based on the results collected so far, the GTTC decided to conduct further analyses.