

## **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 November 2022**

### **Forty-third session**

Geneva, 7-9 December 2022

Item 3 (e) 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-second 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/Add.1, the informal document INF.37 (39th 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) and forty-second (INF.15) session. The informal working group plan to continue their work in the next biennium, aiming on finalisation of the revision of Chapter 3.5 by the end of 2024. Therefore, the informal working group requests the Sub-Committee to agree to carry-over the program of work into the 2023-2024 biennium.

### **Status report**

3. As a follow-up to the forty-second session, the informal working group progressed the revisions and on-going discussions through written procedure and one online meeting. The group made a few further editorial considerations in the definitions of Chapter 3.5. It was agreed to include references to further guidance on weight of evidence to enable conclusion on positive results from in vitro mutagenicity tests, as well as good practice in interpretation of in vivo mutagenicity and genotoxicity tests.

4. Related to the discussion of the criteria of germ cell mutagenicity, a majority of the members of the informal working group would agree to an enlargement of the Category 1A, by moving criterion 1B (c) to 1A, as referring to human evidence. However, other members

raised technical objections to an enlargement of Category 1A and no consensus has been reached yet on this issue. Further, in Category 1B (b) it was agreed to give at least equal weight to *in vivo* somatic and germ cell genotoxicity tests, and revise the current text accordingly.

5. The United States of America prepared a proposal how to simplify the criteria text by moving some more explanatory text to other parts of the chapter, and they also made the comparison to the correspondent text in the criteria for carcinogenicity and reproductive toxicity to seek harmonization across chapters. Currently comments are collected from the group to feed into the continuous criteria discussion.

6. The Genetic Toxicology Technical Committee (GTTC) of the Health and Environmental Science Institute (HESI) have extended their 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. GTTC informs on their progress at each meeting of the informal working group. The results of the study are expected in 2023.

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