

## **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 June 2022**

**Forty-second session**

Geneva, 6-8 July 2022

Item 2 (e) of the provisional agenda

**Work on the Globally Harmonized System (GHS):  
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-first 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).

#### **Status report**

3. The informal working group met three times after the forty-first session. They further elaborated and almost completed the updated list of terminology for clarification of the text related germ cell mutagenicity to be included into the text of Chapter 3.5. They continued the review of the list of test methods with the aim to update the chapter, including the guidance section. The informal working group agreed, in contrary to the intention reported at the forty-first session, not to finalise this work in 2022, to avoid possible inconsistencies between these revisions and the classification criteria.

4. At their thirty-fourth meeting in April 2022, the Working Group of the National Coordinators of the Test Guidelines Programme agreed to the request submitted by the European Commission and the OECD Secretariat, asking for support for the work on the criteria for classification for germ cell mutagenicity to be included in their work plan. Once a proposal to amend the GHS criteria is drafted by the GHS informal working group on germ cell mutagenicity, it will be transmitted to the OECD Expert Group on genotoxicity testing for a review.

5. The Genetic Toxicology Technical Committee (GTTC) of the Health and Environmental Science Institute (HESI) is conducting a 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 prior the end of 2022.

6. The informal working group initiated the discussion on revisions for clarification of the criteria of germ cell mutagenicity in Chapter 3.5, and this discussion will continue in parallel to the work of the GTTC. The informal working group will propose a final wording of the criteria only when the results of the GTTC study is available. Thereafter the review of the OECD will be accommodated. A final adoption of Chapter 3.5 is foreseen in the biennium 2023-2024.

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