

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**

3 December 2021

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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 fortieth 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 (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).

3. The Sub-Committee agreed at the fortieth session that changes on the classification criteria proposed by the informal working group would be sent for review to the OECD Expert Group on Genotoxicity before being considered for final adoption.

Status report

4. The informal working group met once after the fortieth session, and thereafter further work was carried out through written procedure. An updated list of terminology for clarification of the text related germ cell mutagenicity is close to agreement and should be included into the text of Chapter 3.5. The informal working group is also reviewing the list of test methods with the aim to update the chapter, including the guidance section. These two revisions are considered possible to finalize in 2022.

5. The European Commission and the OECD Secretariat submitted a Standard Project Submission Form to request support for the work on the criteria for classification for germ cell mutagenicity to be included in the OECD Test Guidelines Programme. The role of the OECD, acting as a GHS technical focal point in this context, will be to conduct a review of the revised criteria by a relevant OECD expert group. The Working Group of National

Coordinators of the Test Guidelines Programme will be requested to nominate experts for the establishment of a dedicated OECD expert group.

6. The Genetic Toxicology Technical Committee (GTTC) of the Health and Environmental Science Institute (HESI) took the initiative to conduct 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. The results of the study are expected prior the end of 2022.

7. The discussion on revisions for clarification and update of the text in Chapter 3.5 including the criteria of germ cell mutagenicity will continue in parallel to the work of the GTTC. However, considering that the results of the GTTC project may support the final wording of the criteria and thereafter to accommodate the review of the OECD, a final adoption of Chapter 3.5 is not foreseen in this biennium.
