

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

8 December 2020

Thirty-ninth session

Geneva, 9-11 December 2020

Item 3 (i) of the provisional agenda

Classification criteria and related hazard communication:

Other issues

Proposal to create an informal working group on clarification of the criteria for classification for germ cell mutagenicity in category 1B and set up its terms of reference

Transmitted by the observer from the European Union

Background

1. Reference is made to the proposals contained in ST/SG/AC.10/C.4/2020/13 (European Union) on the Clarification of the criteria for classification for germ cell mutagenicity in category 1B, and related informal document INF.7 (Germany) prepared for discussion at the 39th session of the Sub-Committee initially scheduled from 8 to 10 July 2020.
2. Since the session could not be held in July, informal discussions took place during the summer, the observer from the European Union submitted a new document ST/SG/AC.10/C.4/2020/13/Add.1 for the thirty-ninth session indicating that the European Commission proposed creating an informal working group to discuss the issues in-depth prior suggesting a final proposal to the Sub-Committee, as proposed by the expert from Germany in informal document INF.7.
3. Comments received in the GHS workspace during the consultations for the 39th session were supportive to the creation of an informal working group, therefore the European Commission has suggested a proposal for draft terms of reference for the informal working group on the criteria for classification for germ cell mutagenicity.
4. The draft terms of reference would be discussed at the first meeting of the informal working group on the criteria for classification for germ cell mutagenicity, with the aim to submit the terms of reference agreed by the informal working group for approval at the 40th session of the Sub-Committee together with a detailed work programme.
5. The work of the informal working group would be organized by the Joint Research Center (JRC) of the European Commission.

Proposal

6. The following draft terms of reference are proposed as a basis for discussion in the informal working group:
 - (a) Propose an amendment to Chapter 3.5 to:
 - (i) Review the criteria for classification in category 1B, in order to permit the use of other types of data as indirect evidence of interaction with germ cells; such as toxicokinetic data from currently accepted *in vivo* studies and/or supporting evidence from other available studies.

- (ii) Ensure that the wording throughout the text of the chapter is coherent and not redundant and avoid the inconsistent use of the word “mutagenicity” and “heritable”.
 - (iii) Update the chapter according to current state of science, including newly available Test Guidelines. Consider whether to include non-Test Guideline (TG) assays, and regrouping of the tests.
 - (iv) Include paragraphs regarding non-testing methods similar to that in the newly revised Chapter 3.2 and extend the note on read-across to be in line with the revised Chapter 3.2 on skin corrosion/irritation. In addition, indicate that a read-across can be supported by positive results in *in vitro* mammalian mutagenicity assays.
 - (b) Consider any new information relevant to the work provided by other international organizations or institutions, such as OECD or the Health and Environmental Sciences Institute (HESI).
 - (c) Prepare draft amendments and additions to the GHS to facilitate hazard classification using non-animal methods, where appropriate, and consult with the informal working group on non-animal testing methods (NATM) for submission as a proposal in a working document directly to the Sub-Committee.
 - (d) Identify technical errors and/or editorial improvements during the review of chapters that are not related to classification of germ cell mutagenicity and send them to the Practical Classification Issues informal working group (PCI) for submission as a proposal in a working document directly to the Sub-Committee.
 - (e) Report progress to the Sub-Committee as appropriate.
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