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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

Thirty-ninth session
Geneva, 9-11 December 2020
Item 3 (i) of the provisional agenda
Classification criteria and related hazard communication: other issues

Clarification of the criteria for classification for germ cell mutagenicity in category 1B

Transmitted by the European Union*

Addendum

1. The European Commission thanks delegates for submitting comments during the July consultation and wishes to submit an addendum to the original proposal in document ST/SG/AC.10/C.4/2020/13, based on the comments received.

2. In addition to the arguments and modifications presented in document ST/SG/AC.10/C.4/2020/13, we have identified the following issues that would benefit from further consideration:

(a) Issues related to the tests:

(i) Update of Chapter 3.5 with regard to newly available Test Guidelines.

(ii) Inclusion of non-Test Guideline (TG) assays; TGs that have been deleted by the OECD Council and tests that are in the validation pipeline.

(iii) A regrouping of the tests as listed in the current Chapter 3.5.

(b) The wording in 1B (a), as well as the use of the word “heritable” throughout the chapter.

(c) Ensuring that the wording throughout the text is coherent and not redundant. For instance, if we delete the word “heritable” in 1B (a), so that the statement would allow the use of any in vivo germ cell test, then the word “mutagenicity/” should also be deleted in 1B (b).

* 2020 (A/74/6 (Sect.20) and Supplementary, Subprogramme 2.

(d) Issues related to read-across and non-testing methods:

(i) Extending the note on read-across to the application of read-across to all categories, also in the absence of testing data, 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.

(ii) Inclusion of paragraphs regarding non-testing methods similar to that in the newly revised Chapter 3.2.

3. We suggest, in accordance with the proposal by Germany in informal document INF.7, to establish an informal working group to discuss changes proposed in the working document ST/SG/AC.10/C.4/2020/13 and its addendum in the next biennium. The European Commission would volunteer to take the lead of such informal working group with the mandate to discuss the proposed revisions and any text in Chapter 3.5 related to these changes with the aim to achieve a coherent and clear text.