

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

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Item 3 (c) of the provisional agenda

Work on the Globally Harmonized System of Classification and
Labelling of Chemicals: use of non-animal testing methods
for classification of health hazards

Consequential amendments to the proposal in ST/SG/AC.10/2022/15 following the amendments to Chapter 3.4 in informal document INF.8

Transmitted by the experts from the United Kingdom and the Netherlands
on behalf of the informal working group on the use of non-animal testing
methods for classification of health and environmental hazards

Introduction

1. This document proposes consequential amendments to the text of sections 3.3.2.3.3, 3.3.2.4.2 and 3.3.2.8.1 of Chapter 3.3 proposed in ST/SG/AC.10/C.4/2022/15. These changes are necessary following the additional amendments proposed in informal document INF.8 to the revised text of Chapter 3.4 in document ST/SG/AC.10/C.4/2022/14 (and consolidated in INF.3/Rev.1).

2. These amendments are proposed in full in paragraphs 3 to 5 below, with new or replacement text shown in **bold black and underlined**, and deleted text (from that proposed in ST/SG/AC.10/C.4/2022/15) is shown in underlined black ~~striketrough~~ text. Text shown in plain black is the text previously proposed in ST/SG/AC.10/C.4/2022/15 that remains unchanged.

Proposed amendments to ST/SG/AC.10/2022/15

3. Amend paragraph 3.3.2.3.3 as follows:

[“3.3.2.3.3 ~~Some evidence can be used individually and in defined approaches.~~ **Individual** Evidence ~~considered used~~ within a defined approaches should ~~then not also be~~ **considered as an additional line of evidence** ~~used individually~~ within a weight of evidence assessment.”]

4. Amend paragraph 3.3.2.4.2 as follows:

“3.3.2.4.2 *In vitro/ex vivo* methods in 3.3.2.4.1 with the result “no stand-alone prediction can be made” should within Tier 2 only be used in combination with other types of data in defined approaches. ~~When already considered within a defined approach, *in vitro/ex vivo* methods should not be considered as an additional line of evidence.”~~”

5. Amend paragraph 3.3.2.8.1 as follows:

“3.3.2.8.1 Classification, including the conclusion not classified, can be based on non-test methods, with due consideration of reliability and applicability, on a case-by-case basis. ~~Specific non test methods may also be used in a defined approach. When~~”

~~already considered within a defined approach, these specific non-test methods should not be considered as an additional line of evidence.~~ Non-test methods include computer models predicting qualitative structure-activity relationships (structural alerts, SAR) or quantitative structure-activity relationships (QSARs), computer expert systems, and read-across using analogue and category approaches.”

Action and next steps

6. The Sub-Committee is invited to consider the additional amendments in addition to the proposal in ST/SG/AC.10/C.4/2022/15 listed in paragraphs 3 to 5 above.
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