

## 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 2 (j) of the provisional agenda

Work on the Globally Harmonized System of  
Classification and Labelling of Chemicals:

Other matters

## Reference to “non-observed effect concentration” in chapter 4.1, category chronic 4

Transmitted by the United Nations Institute for Training and  
Research (UNITAR)

### Introduction

1. The classification criteria in chapter 4.1 of the GHS (Rev.10) for category Chronic 4 in table 4.1.1 (c) reads as follows:

(c) “Safety net” classification

**Category Chronic 4:**

Poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility, and which are not rapidly degradable and have a  $\log K_{ow} \geq 4$ , indicating a potential to bioaccumulate, will be classified in this category unless other scientific evidence exists showing classification to be unnecessary. Such evidence would include an experimentally determined  $BCF < 500$ , or a chronic toxicity NOECs  $> 1 \text{ mg/l}$ , or evidence of rapid degradation in the environment.

2. The underlined part is contradictory from a linguistic point of view and also with respect to texts in other parts of chapter 4.1 and annex 9.

3. As written, the text in table 4.1.1 (c) can be interpreted, and clarified accordingly, as shown below:

- (a) If the intended meaning is that there is only one NOEC, the text should read: “...a chronic toxicity NOEC  $> 1 \text{ mg/l}$ .”;
- (b) If there intended meaning is that there may be several NOECs in the scope of the criteria, the text should read: “...~~a~~ chronic toxicity NOECs  $> 1 \text{ mg/l}$ ...”

4. Existing text in other parts of chapter 4.1 and annex 9, seems to confirm that from a scientific point of view, the criteria in table 4.1.1 (c) is meant to refer to more than one NOEC. For instance:

• **Chapter 4.1:**

- Paragraph 4.1.2.7.2, second to last sentence: “...showing NOECs...”
- Table 4.1.2, chronic 4 text box: “...unless NOECs  $> 1 \text{ mg/l}$ ”

• **Annex 9:**

- A9.2.4.1 (c): “chronic aquatic toxicity (NOECs and/or...”
- A9.3.2.2, last sentence of 2nd section in italics: “The NOECs or other ...”
- A9.3.3.2.3 (c), 2nd to last sentence: “...it is likely that NOECs from...”
- A9.3.3.2.4, 1st sentence: “...the chronic toxicity (NOECs).”.

5. It is worth noting that in other regulatory texts, e.g.: the European Union’s Classification, Labelling and Packaging Regulation (CLP Regulation); the criteria for chronic 4 appears as shown in paragraph 3 (b) above (i.e. “chronic toxicity NOECs > 1 mg/l”.

6. The French version of the GHS also refers to several NOECs (i.e: “...ou des CSEO de toxicité chronique...”), in alignment with the interpretation proposed in paragraph 3 (b) above.

7. Thus, it seems evident that the text should read “NOECs” and the “a” in table 4.1.1 (c) should be removed.

## **Proposal**

8. In the last sentence in table 4.1.1 (c), replace “or a chronic toxicity NOECs > 1 mg/l” by “or chronic toxicity NOECs > 1 mg/l”.

9. The sentence as amended would read: “Such evidence would include an experimentally determined BCF < 500, or chronic toxicity NOECs > 1 mg/l, or evidence of rapid degradation in the environment.”.

10. The Sub-Committee is invited to consider the proposal in this document and to advise on whether it should be considered as a correction to Rev.10 or an amendment.