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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

Forty-third session

Geneva, 7-9 December 2022 Item 3 (f) of the provisional agenda

Work on the Globally Harmonized System of Classification and Labelling of Chemicals: Practical classification issues (proposed amendments to the Globally Harmonized System)

Proposal to address issues from the program of work for the practical classification issues informal correspondence group

Transmitted by the expert from the United States of America on behalf of the practical classification issues informal correspondence group¹

Purpose

1. This working document is the outcome of discussions on work item (g) from the practical classification issues informal correspondence group (PCI) program of work (informal document INF.31 (39th session)), which addresses the issues referred to the PCI from the non-animal test methods (NATM) informal working group.

Background

2. As reported at the forty-second session (see informal document INF.19 (42nd session)), the PCI informal group has made significant progress on items referred to it from the NATM informal working group and has reached consensus on a path forward for eight of the nine items (see Annex I of INF.19 for the full list and description of items). The only item not included in this document is item 3, which the group decided to pause pending further work on the PCI program of work issue (f). The proposals in this working document are taken directly from Annex 2 of INF.19 since no feedback was provided at the informal document INF.19 (42nd session). In addition, as noted in informal document INF.19, the PCI informal group continued to work on items 2 and 7 and has included proposals to address them in this document.

¹ A/75/6 (Sect.20), para. 20.51

Proposed amendments to address Item 1

- 3. For consistency, the group reviewed the different terms weight of evidence approach/determination/evaluation/analysis throughout the GHS, and where appropriate, revised the text to weight of evidence "assessment". As part of the review, it was agreed that in some cases it was more appropriate to retain the term weight of evidence "approach" and as such, these cases are not included in the proposals below.
- 4. The proposed amendments related to Issue 1 are as follows:
 - In 1.3.2.4.8, replace "determinations" with "assessments" in the last sentence.
 - In 1.3.2.4.9.2, replace "determination" with "assessment" in the last sentence.
 - In 1.3.2.4.9.5, replace "determination" with "assessment" in the first sentence.
 - In 3.1.2.3, replace "approach" with "assessment" in the last sentence.
 - In 3.2.5.3.5.2.6, replace "approach" with "assessment" in the second sentence.
 - In 3.4.2.1.1.3, replace "approach" with "assessment" twice.
 - In 3.4.3.1, replace "evaluation" with "assessment" in the first sentence.
 - In 3.5.5.1.1 Decision logic 3.5.1 for substances, replace "approach" with "assessment" in the second and third textboxes down.
 - In 3.6.5.3.2, replace "analysis" with "assessment" in the second sentence.
 - In 3.6.5.3.2.1, replace "evaluation" with "assessment" in the last sentence.
 - In 3.6.5.1 Decision logic 3.6.1 for substances, replace "approach" with "assessment" in the second and third textboxes down.
 - In 3.7.2.2.1, replace "an assessment of the total weight of evidence" with "a total weight of evidence assessment" in the first sentence.
 - In 3.7.2.3.1, replace "an assessment of the total weight of evidence" with "a total weight of evidence assessment" in the first sentence.
 - In 3.7.2.4.1, replace "approach" with "assessment" in the fourth sentence.
 - In 3.7.5.1.1 Decision logic 3.7.1 for substances, replace "approach" with "assessment" in the second and third textboxes down.
 - In Note a to Table 3.8.1, replace "approach" with "assessment" in the first sentence.
 - In Note b to Table 3.8.1, replace "evaluation" with "assessment" in the second sentence.
 - In 3.8.2.1.10.1, replace "approach" with "assessment".
 - In 3.8.2.2.1 (d), replace "evaluation" with "assessment" in the last sentence.
 - In 3.8.3.2, replace "evaluation" with "assessment" in the first sentence.
 - In 3.8.5.1 Decision logic 3.8.1, replace "approach" with "assessment" in the fourth, fifth and sixth textboxes down.
 - In 3.9.2.9.8, replace "approach" with "assessment" in the first sentence.
 - In 3.9.2.10.1, replace "approach" with "assessment".
 - In 3.9.3.2, replace "evaluation" with "assessment" in the first sentence.
 - In 3.9.5.1 Decision logic 3.9.1, replace "approach" with "assessment" in the fourth and fifth textboxes.
 - In 4.1.2.5, replace "approach" with "assessment" in the fourth sentence.
 - In A9.4.3.5.1, delete the quotation marks before weight and after approach and replace "approach" with "assessment" in the second sentence.

- In A9.4.3.6, replace "approach" with "assessment in the third sentence.
- In A9.5.4.1, delete the quotation marks before weight and after approach and replace "approach" with "assessment" in the second sentence.
- 5. The following proposed amendments related to Issue 1 are only needed if the NATM informal working group's proposal to amend the hazard class "skin sensitization" in Chapter 3.4 are not adopted:
 - In 3.4.2.2.1.3, replace "approach" with "assessment" twice.
 - In 3.4.2.2.4.1, replace "using" with "in" and "approach" with "assessment"

Proposed amendments to address Item 2

- 6. Clarify in paragraphs 3.2.2.8.1, 3.3.2.10.1, and 3.3.5.3.4.2 the meaning of the term "elements".
- 7. The proposed amendments related to Item 2 are as follows:
 - In paragraphs 3.2.2.8.1 and 3.3.2.10.1 delete "initial" in the first sentence.
 - In paragraphs 3.2.2.8.1, 3.3.2.10.1, and 3.3.5.3.4.2 replace "elements" with "tiers as well as information within a tier" in the first sentence.

Proposed amendments to address Item 4

- 8. Clarify in paragraphs 3.2.3.3.1 and 3.3.3.3.1 that the use of the term "tiered approach" is referring to the mixture tiered approach and not the substance tiered approach.
- 9. The proposed amendments related to Item 4 are as follows:
 - In 3.2.3.3.1 and 3.3.3.3.1, at the end of the first paragraph after "tiered approach" insert "to mixtures (see 1.3.2.3)"

Proposed amendments to address Item 5

- 10. Clarify in paragraphs 3.2.3.3.4 and 3.3.3.3.4 that care must be taken when classifying mixtures that contain the listed types of substances as opposed to taking care when classifying the substances themselves; and use the more consistently used term "substances" instead of "chemicals".
- 11. The proposed amendments related to Item 5 are as follows:
 - In 3.2.3.3.4 and 3.3.3.3.4, insert "mixtures containing" after "classifying" and replace "chemicals" with "substances" in the first sentence.

Proposed amendments to address Item 6

- 12. Clarify the ambiguity in the last sentence in paragraphs 3.2.3.3.5 and 3.3.3.3.5.
- 13. The proposed amendments related to Item 6 are as follows:
 - In 3.2.3.3.5 and 3.3.3.3.5, delete the last sentence of the paragraph (i.e., beginning with "In those cases").

Proposed amendments to address Item 7

- 14. Clarify the inconsistent terminology use in the following 3 cases:
 - (a) Inconsistency in the last sentence of the Substantially similar bridging principle.

- (b) Use of the term "aerosol" at the beginning of the Aerosols bridging principle.
- (c) Inconsistency in the use of the term hazards vs. properties in paragraphs 3.2.3.3.1 and 3.3.3.3.1.
- 15. The proposed amendments related to Item 7 are as follows:
 - (a) Inconsistency in the last sentence of the "substantially similar" bridging principle:
 - In 3.3.3.2.6, 3.4.3.2.6, 3.5.3.2.4, 3.6.3.2.4, 3.7.3.2.4, 3.8.3.3.6 and 3.9.3.3.6 replace "by testing" with "based on test data" in the last sentence.
 - In 3.3.3.2.6 replace "assigned" with "classified" in the last sentence.
 - In 3.1.3.5.6, 3.4.3.2.6, 3.6.3.2.4, 3.7.3.2.4, 3.8.3.3.6, 3.9.3.3.6, 3.10.3.2.6, and 4.1.3.4.6 replace "assigned" with "classified in" in the last sentence.
 - (b) Use of the term "aerosol" at the beginning of the "Aerosols" bridging principle:
 - In 3.1.3.5.6, 3.2.3.2.7, 3.3.3.2.7, 3.4.3.2.7, 3.8.3.3.7, 3.9.3.3.7 replace "aerosol" with "aerosolised" at the beginning of the sentence.
 - In 3.1.3.5.6, 3.2.3.2.7, 3.3.3.2.7, 3.4.3.2.7, 3.8.3.3.7, 3.9.3.3.7 replace "non-aerosolized" with "non-aerosolised" in the first sentence.
 - In 3.1.3.5.6, 3.8.3.3.7, 3.9.3.3.7 replace "aerosolized" with "aerosolised" in the last sentence.
 - (c) Inconsistency in the use of the term hazards vs. properties in paragraphs 3.2.3.3.1 and 3.3.3.3.1.

In 3.3.3.3.1, replace "properties" with "hazards" and delete "the" before "mixtures".

Proposed amendments to address Item 8

- 16. Clarify the inconsistent use of the:
 - · Terms hazard class vs. endpoint effects,
 - Order of the terms "cut-off values" and "concentration limits",
 - Reference to section 1.3.3.2, and
 - Reference to another paragraph and Figure in paragraphs 3.2.3.3.5 and 3.3.3.3.5
- 17. The proposed amendments related to Item 8 are as follows:
 - In 3.2.3.3.5:

Replace "concentration limits/cut-off values" with "cut-off values/concentration limits" in the first sentence.

Delete "Classification of hazardous substances and mixtures – Use of cut-off values/Concentration limits" inside the parentheses in the second sentence.

Delete the parentheses around "1.3.3.2" at the end of the sentence.

Replace "concentration cut-off values" with "cut-off values/concentration limits" in the third sentence.

Replace "described in 3.2.3 and illustrated in Figure 3.2.1" with "referred to in 3.2.3, Figure 3.2.1 and explained in detail in this chapter." in the last sentence.

• In 3.3.3.3.5:

Replace "irreversible/reversible eye effects" with "serious eye damage/eye irritation" in the first sentence.

Delete "Use of cut-off values/Concentration limits" inside the parentheses in the second sentence.

Replace "irreversible/reversible eye effects" with "serious eye damage/eye irritation" and "concentration/cut-off levels" with "cut-off values/concentration limits" in the third sentence.

Proposed amendments to address Item 9

- 18. For consistency, update the hazard communication section of each physical, health and environmental chapter to refer to the label elements table.
- 19. The proposed amendments related to Item 9 are as follows:
 - In 2.1.3, insert "Table 2.1.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
 - In 2.2.3.1, insert "Table 2.2.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
 - In 2.3.1.3, insert "Table 2.3.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
 - In 2.3.2.3, insert "Table 2.3.4 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
 - In 2.4.3, insert "Table 2.4.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
 - In 2.5.3, insert "Table 2.5.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
 - In 2.6.3, insert "Table 2.6.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
 - In 2.7.3, insert "Table 2.7.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
 - In 2.8.3, insert "Table 2.8.1 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
 - In 2.9.3, insert "Table 2.9.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
 - In 2.10.3, insert "Table 2.10.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
 - In 2.11.3, insert "Table 2.11.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
 - In 2.12.3, insert "Table 2.12.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.

- In 2.13.3, insert "Table 2.13.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
- In 2.14.3, insert "Table 2.14.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
- In 2.15.3, insert "Table 2.15.1 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
- In 2.16.3, insert "Table 2.16.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
- In 2.17.3, insert "Table 2.17.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.

• In 3.1.4.1:

Delete the last sentence of the paragraph.

Insert "Table 3.1.3 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.

• In 3.2.4:

Delete the last sentence of the paragraph.

Insert "Table 3.2.5 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.

- In 3.3.4, Insert "Table 3.3.5 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
- In 3.4.4.1:

Delete the last sentence of the paragraph.

Insert "Table 3.4.6 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.

• In 3.5.4:

Delete the last sentence of the paragraph.

Insert "Table 3.5.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.

• In 3.6.4:

Delete the last sentence of the paragraph.

Insert "Table 3.6.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.

• In 3.7.4, insert "Table 3.7.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.

- In 3.8.4.1, insert "Table 3.8.3 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
- In 3.9.4, insert "Table 3.9.4 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
- In 3.10.4.1:

Delete the last sentence of the paragraph.

Insert "Table 3.10.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.

- In 4.1.4, insert "Table 4.1.6 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.
- In 4.2.3, insert "Table 4.2.2 presents specific label elements for substances and mixtures classified into this hazard class based on the criteria in this chapter." at the end of the paragraph.

Action requested

- 20. The Sub-Committee is invited to consider the proposed amendments to the GHS as set out in this document in the following paragraphs:
 - Item 1 proposed amendments are provided in paragraph 4.
 - Item 1 proposed amendments are provided in paragraph 5.
 - Item 2 proposed amendments are provided in paragraph 7.
 - Item 4 proposed amendments are provided in paragraph 9.
 - Item 5 proposed amendments are provided in paragraph 11.
 - Item 6 proposed amendments are provided in paragraph 13.
 - Item 7 proposed amendments are provided in paragraph 15.
 - Item 8 proposed amendments are provided in paragraph 17.
 - Item 9 proposed amendments are provided in paragraph 19.