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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-eighth session
Geneva, 7-9 July 2025
Item 2 (f) of the provisional agenda
Work on the Globally Harmonized System (GHS): Practical classification issues (proposed amendments to the Globally Harmonized System)

Proposal to clarify the bridging principles in chapters 3.2, 3.3 and 3.4

Transmitted by the experts from Germany and the United States of America on behalf of the practical classification issues informal working group (PCI IWG)*

I. Purpose

1. At the forty-third session, the Sub-Committee approved addressing the bridging principles in chapters 3.2, 3.3 and 3.4 of the practical classification issues informal working group's (PCI IWG) program of work (see INF.34)[1]. The proposed amendments provide clarifications of the use of the bridging principles in line with chapter 1.3 and will bring consistency and harmonize the interpretation of the bridging principles in chapters 3.2, 3.3, and 3.4 (item 4 of the programme of work of the IWG).

II. Background

2. The aim of this work item as agreed in the thirty-ninth session and laid down in the programme of work (INF.34 of the forty-third session) and terms of reference, is to develop and propose a scientifically sound procedure for the tiered approach for classification of mixtures in chapters 3.2 to 3.4 allowing use of the available data in the most appropriate possible way. The following three work streams were set out in the terms of reference INF.23 (thirty-ninth session session)[2]:

(a) Workstream 1: Analysis of the status quo;

* A/79/6 (Sect. 20), Table 20.6.

1 INF.34 (43rd session)

2 INF.23 (39th session)

(b) Workstream 2: Identify a procedure for the tiered approach for mixture classification in chapters 3.2 to 3.4 which would allow to use the available data in the most appropriate way; and

(c) Workstream 3: Explore the relevant sections in chapter 1.3 with reference to the results of workstream 2 and propose additional or modifying text, if deemed necessary.

3. The IWG started its work on this work item in March 2022 with the circulation of the first thought starter on workstream 1 and the first web meeting. Surveys, live in the meetings and after ensuring the participation of all IWG members, were used to structure the discussion including the discussion of examples raising specific aspect on considerations/hierarchy of different data types in relation to the bridging principles. A second thought starter on workstream 2 was circulated to the IWG members in June 2022.

4. To date the IWG discussed the tiered approach for mixture classification and the hierarchy of data versus options for an overall weight of evidence assessment for mixtures that includes bridging and ingredient-based information in different chapters. In addition, the use of "should" and "may" was discussed with regard to their interpretation and impact on the implementation of the tiered approach. In June 2022 (with the second thought starter) the group focussed their discussions on the relevance and reliability of different lines of evidence available for mixture classification. The understanding of the term "substantially similar mixtures" based on different examples was discussed.

5. The IWG completed those discussions and no consensus was reached to amend paragraph 1.3.2.3.1 and/or the character of the tiered approach for mixtures (workstream 3).

6. During those discussions it was noted that there were differences in understanding in relation to the intent, scope and reliability of several bridging principles. Therefore, the IWG worked on amending those to clarify their intent.

7. A snapshot of the discussions focussing on relevant sections of chapter 3.2 and consequential amendments in chapters 3.3 and 3.4 was presented at the forty-sixth and forty-seventh sessions of the Sub-Committee (INF.19 part 1[3] and INF.26 respectively [4]).

8. A short overview on the discussions and rationale of the proposed amendments, focussing on relevant sections of chapter 3.2 and consequential amendments in chapters 3.3 and 3.4 is provided below:

(a) Classification of mixtures when data are not available for the complete mixture: bridging principles

There was agreement to delete the reference to additional testing "in animals" since it does not reflect the more recently introduced non-animal methods, which may be used. Furthermore, there was agreement to add a reference to section 1.3.2.4.6 to add clarity. The IWG considered common phrases used in the GHS to refer to sections before deciding that "in line with" is most suitable.

(b) Dilution

The IWG considered the questions below and concluded as follows:

(i) *Discussed but original wording retained:*

(a) The terms "least skin corrosive/irritant original ingredient" (3.2.3.2.2) and "least seriously eye damaging/eye irritant original ingredient" (3.3.3.2.2) were considered inappropriate as soon as a mixture contained a diluent (e.g. water). Consequently, a dilution of a skin corrosive or seriously eye damaging mixture with an irritant would not be encompassed by the bridging principle. There was agreement amongst the experts that in such cases, bridging should not be applied and the ingredient-based

[3] INF.19 part 1 (46th session)
[4] INF.26 (47th session)

approach should instead be used. The group also discussed whether a similar phrase should be introduced in chapter 3.4 where the current wording restricts the use of diluents to non-sensitizing substances. Since this would constitute a reduction of the protectiveness of this principle, there was no agreement to the proposed amendment of the current text and the existing text was retained.

(b) The IWG discussed whether in relation to 3.2.3.2.2 the term "skin irritancy" should be replaced by "skin irritant properties". In order to maintain wording consistent with the other chapters under review, there was agreement to retain the original wording.

(c) The last sentence of the section on dilution in 3.2.3.2.2 and 3.3.3.2.2 refers to the "method explained in 3.2.3.3" and "method explained in 3.3.3.3", respectively, as an alternative approach to be used. The IWG discussed that this reference to the ingredient-based approach may contradict the tiered approach as laid down in paragraph 1.3.2.3.1. The experts also saw the need to offer this alternative where mixtures are substantially diluted. In conclusion, there was agreement to retain the current wording.

(ii) *Discussed and changed*

There was agreement to align the wording in 3.2.3.2.2 with 3.3.3.2.2 by placing the word "classification" before "skin corrosivity/irritancy"

(c) Batching (paragraphs 3.2.3.2.3, 3.3.3.2.3 and 3.4.3.2.3)

(i) The term "variation" describing differences between batches was discussed with respect to clarity. There was agreement in the IWG to replace the term "variation" with "deviation" and include an accompanying description/explanatory example: "deviation (e.g. caused by variation in an ingredient´s composition or processing conditions)".

(ii) There was agreement to amend the last sentence by adding "assessment of the".

(d) Concentration of mixtures of the highest skin corrosion/irritation or eye damage/eye irritation or sensitizing category/sub-category

(i) The IWG agreed to add clarifying wording to the heading of 3.2.3.2.4 and 3.3.3.2.4 to align the headings of these sections in chapters 3.2, 3.3 and 3.4.

(ii) There was agreement to add wording in this section to add clarity to the reader's understanding in relation to the different categories/sub-categories for each chapter. In addition, in each sentence the process of concentrating a tested mixture is clarified with the term "by reducing or removing an ingredient of less severe or no classification". In addition, specific to section 3.2.3.2.4, there was agreement to add new explanatory text on Category 3.

(e) Interpolation within one hazard category

(i) There was agreement to change the naming of three mixtures from "A, B and C" to "(i), (ii), and (iii)" in the chapters under consideration (3.2, 3.3 and 3.4).

(ii) To avoid redundancy an additional description of (iii) ("and where untested mixture C (iii) has the same toxicologically active ingredients as mixtures A (i) and B (ii)") was deleted in 3.2.3.2.5.

(iii) In relation to 3.2.3.2.5 and 3.3.3.2.5 it was discussed if the sentence "The sum of the concentrations of the toxicologically active ingredients in the same hazard category in (iii) should be equal to or below (i) and (ii)." should be added. No consensus was reached in the IWG. Alternatively, two options to add a clarifying statement were discussed and the feedback of the Sub-Committee was requested as per INF.26 (forty-seventh session). The members of the IWG and the Sub-Committee expressed a preference for option 2 as reflected in the report of the Sub-Committee on its forty-seventh session[5].

(f) Substantially similar mixtures

(i) For 3.2.3.2.6 and 3.3.3.2.6 (substantially similar mixtures) the IWG discussed three different options to clarify sub-paragraph (b). There was a preference amongst the IWG experts to retain the original wording. The IWG sought the feedback of the Sub-Committee as per INF.26 (forty-seventh session) and the Sub-Committee confirmed the preference noted by the IWG to retain the wording as is (ST/SG/AC.10/C.4/94, paragraph 33)[5].

(ii) The IWG experts discussed and agreed that ingredient B is the driving agent. This was confirmed by the chief author of this principle and considered a logical implication from the mixture ingredients being grouped into A, B and C. However, the implicit consequence of grouping was deemed insufficiently clear. Also as discussed, extensive testing would be needed to understand which ingredient (i.e., B) is driving the classification of a mixture. Furthermore, even with extensive testing, confirmation that a single substance/ingredient is driving the classification may not be possible. Therefore, the group agreed on adding a new sentence to reflect this and to clarify that B contains all substances contributing to the classification for the endpoint. This new sentence comprises now sub-section "(c)". Consequently, the current/original wording of sub-section "(c)" was agreed to be redundant and is proposed for deletion.

(iii) To further clarify this principle the sentence "In the context of this bridging principle, ingredients A, B and C could each consist of one or multiple substances or mixtures" was added for each endpoint.

(iv) In 3.2.3.2.5 and 3.3.3.2.5 there was agreement to delete "and i.e. they are in the same hazard category".

9. It is noted that as a result of the potential changes in chapters 3.2 to 3.4, consequential amendments need to be considered for chapters 3.1 (Acute toxicity), 3.5 (Germ cell mutagenicity), 3.6 (Carcinogenicity), 3.7 (Reproductive toxicity), 3.8 (Specific target organ toxicity – single exposure), 3.9 (Specific target organ toxicity – repeated exposure), 3.10 (Aspiration hazard) and 4.1 (Hazardous to the aquatic environment).

10. The IWG concluded their discussions on work item 4 (including the feedback from the Sub-Committee received at the forty-seventh session on the options proposed by IWG). The proposed amendments to the GHS resulting from this work are listed below

III. Proposal

11. The IWG invites the Sub-Committee to consider the following proposed amendments to chapters 3.2, 3.3 and 3.4 of the GHS. For the full text of the amended paragraphs showing all the changes listed below refer to informal document INF.5.

[5] See ST/SG/AC.10/C.4/94, paragraph 33.

Chapter 3.2

3.2.3.2.1 At the end of the paragraph replace: “in animals” by “ (in line with 1.3.2.4.6).”

3.2.3.2.2 In the first sentence, replace “which has an equivalent or lower skin corrosivity/irritancy classification” by “which has an equivalent or lower classification for skin corrosivity/irritancy than”.

3.2.3.2.3 In the first sentence replace “variation” by “deviation (e.g. caused by variation in an ingredient´s composition or processing conditions)”. In the last sentence, replace “new classification” by “new assessment of the classification”.

3.2.3.2.4 Amend to read as follows:

“3.2.3.2.4 *Concentration of mixtures of the highest skin corrosion/irritation category/sub-category*

3.2.3.2.4.1 If a tested mixture classified in Category 1 or the highest sub-category (sub-category 1A) for skin corrosion is concentrated by reducing or removing an ingredient of less severe or no classification for skin corrosion/irritation, the more concentrated untested mixture should be classified in Category 1 or the highest sub-category (sub-category 1A), respectively, without additional testing.

3.2.3.2.4.2 If a tested mixture classified in Category 2 for skin irritation is concentrated by reducing or removing an ingredient of less severe or no classification and does not contain skin corrosive ingredients, the more concentrated untested mixture should be classified for skin irritation (Category 2) without additional testing.

3.2.3.2.4.3 If a tested mixture classified in Category 3 for mild skin irritation is concentrated by reducing or removing an ingredient of no classification and does not contain skin irritant and corrosive ingredients, the more concentrated untested mixture should be classified for mild skin irritation (Category 3) without additional testing.”.

3.2.3.2.5 Amend to read as follows:

“3.2.3.2.5 *Interpolation within one hazard category*

3.2.3.2.5.1 For three mixtures (i), (ii) and (iii) with identical ingredients, where mixtures (i) and (ii) have been tested and are in the same skin corrosion/irritation category, but the untested mixture (iii) has concentrations of the individual toxicologically active ingredients intermediate to the concentrations in mixtures (i) and (ii), then mixture (iii) is assumed to be in the same skin corrosion/irritation category as (i) and (ii).

3.2.3.2.5.2 The sum of the concentrations of the corrosive ingredients in mixture (iii) should be intermediate to the sum of the concentrations of the corrosive ingredients in mixtures (i) and (ii); and, the sum of the concentrations of the irritant ingredients in mixture (iii) should be intermediate to the sum of the concentrations of the irritant ingredients in mixtures (i) and (ii).”.

3.2.3.2.6 Amend to read as follows:

“3.2.3.2.6 *Substantially similar mixtures*

3.2.3.2.6.1 Given the following:

(a) Two mixtures: (i) A + B;

(ii) C + B;

(b) The concentration of ingredient B is essentially the same in both mixtures;

(c) B is the ingredient driving the skin corrosion/irritation potential of mixtures (i) and (ii) and contains all substances classified for skin corrosion/irritation.

(d) Data on skin corrosion/irritation for A and C are available and substantially equivalent and A and C are not expected to affect the skin corrosion/irritation potential of B;

3.2.3.2.6.2 If mixture (i) or (ii) is already classified based on test data, then the other mixture can be classified in the same hazard category.

3.2.3.2.6.3 In the context of this bridging principle, ingredients A, B, and C could each consist of one or multiple substances or mixtures.".

Chapter 3.3

3.3.3.2 At the end of the paragraph replace: "in animals" by "(in line with 1.3.2.4.6)."

3.3.3.2.3 In the first sentence replace "variation" by "deviation (e.g. caused by variation in an ingredient´s composition or processing conditions)". In the last sentence, replace "new classification" by "new assessment of the classification".

3.3.3.2.4 Amend to read as follows:

"3.3.3.2.4 *Concentration of mixtures of the highest serious eye damage/eye irritation category/sub-category*

3.3.3.2.4.1 If a tested mixture classified for serious eye damage (Category 1) is concentrated, by reducing or removing an ingredient of less severe or no classification for eye damage/eye irritation, the more concentrated untested mixture should be classified for serious eye damage (Category 1) without additional testing.

3.3.3.2.4.2 If a tested mixture classified for eye irritation (Category 2 or 2A) is concentrated by reducing or removing an ingredient of less severe or no classification and does not contain serious eye damage ingredients, the more concentrated untested mixture should be classified in the same category (Category 2 or 2A) without additional testing."

3.3.3.2.5 Amend to read as follows:

"3.3.3.2.5 *Interpolation within one hazard category*

3.3.3.2.5.1 For three mixtures (i), (ii) and (iii) with identical ingredients, where mixtures (i) and (ii) have been tested and are in the same serious eye damage/irritation category, but the untested mixture (iii) has concentrations of individual toxicologically active ingredients intermediate to the concentrations in mixtures (i) and (ii), then mixture (iii) is assumed to be in the same serious eye damage/eye irritation category as (i) and (ii).

3.3.3.2.5.2 The sum of the concentrations of the eye damaging ingredients in mixture (iii) should be intermediate to the sum of the concentrations of the corrosive ingredients in mixtures (i) and (ii); and, the sum of the concentrations of the eye irritating ingredients in mixture (iii) should be intermediate to the sum of the concentrations of the irritant ingredients in mixtures (i) and (ii)..

3.3.3.2.6 Amend to read as follows:

"3.3.3.2.6 *Substantially similar mixtures*

3.3.3.2.6.1 Given the following:

(a) Two mixtures: (i) A + B;
(ii) C + B;

(b) The concentration of ingredient B is essentially the same in both mixtures;

(c) B is the ingredient driving the serious eye damage/irritation potential of mixtures (i) and (ii) and contains all substances classified for serious eye damage/irritation.

(d) Data on serious eye damage/irritation for A and C are available and substantially equivalent and A and C are not expected to affect the serious eye damage/irritation potential of B;

3.3.3.2.6.2 If mixture (i) or (ii) is already classified based on test data, then the other mixture can be classified in the same hazard category.

3.3.3.2.6.3 In the context of this bridging principle, ingredients A, B, and C could each consist of one or multiple substances or mixtures."

Chapter 3.4

3.4.3.2.1 At the end of the paragraph replace "in animals" by "(in line with 1.3.2.4.6)."

3.4.3.2.3 In the first sentence replace "variation" by "deviation (e.g. caused by variation in an ingredient´s composition or processing conditions)". In the last sentence, replace "new classification" by "new assessment of the classification".

3.4.3.2.4 After "is increased," insert "by reducing or removing an ingredient of less severe or no classification,".

3.4.3.2.5 Amend to read as follows:

"3.4.3.2.5 *Interpolation within one hazard category/sub-category*

For three mixtures (i), (ii) and (iii) with identical ingredients, where mixtures (i) and (ii) have been tested and are in the same category/sub-category but the untested mixture (iii) has concentrations of individual toxicologically active ingredients intermediate to the concentrations in mixtures (i) and (ii), then mixture (iii) is assumed to be in the same category/sub-category as (i) and (ii).".

3.4.3.2.6 Amend to read as follows:

"3.4.3.2.6 *Substantially similar mixtures*

3.4.3.2.6.1 Given the following:

(a) Two mixtures: (i) A + B;
(ii) C + B;

(b) The concentration of ingredient B is essentially the same in both mixtures;

(c) B is the ingredient driving the skin sensitizing potential of mixtures (i) and (ii) and contains all substances classified for skin sensitization.

(d) Data on sensitization for A and C are available and substantially equivalent and A and C are not expected to affect the sensitizing properties of B;

3.4.3.2.6.2 If mixture (i) or (ii) is already classified based on test data, then the other mixture can be classified in the same hazard category.

3.4.3.2.6.3 In the context of this bridging principle, ingredients A, B, and C could each consist of one or multiple substances or mixtures.".