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| **UN/SCEGHS/46/INF.6** |
| **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** **4 June 2024**  **Forty-sixth session**  Geneva, 3-5 July 2024  Item 2 (j) of the provisional agenda  **Work on the Globally Harmonized System of Classification  and Labelling of Chemicals: other matters** |

Subcategorization in the GHS

Note by the secretariat

I. Introduction

1. GHS hazard classification involves assignment of hazard classes and categories in accordance with the classification criteria defined in the GHS.

2. Five hazard classes in the GHS offer a single hazard category for classification (category 1). These are: oxidizing gases (chapter 2.4), pyrophoric liquids (chapter 2.9), pyrophoric solids (chapter 2.10), corrosive to metals (chapter 2.16) and hazardous to the ozone layer (chapter 4.2).

3. For all other hazard classes, the GHS offers more than one hazard category. Additionally, for several of these hazard classes, hazard categories are further divided into subordinate categories/subcategories (e.g. 1A, 1B, 1C, 2A, 2B) that may be implemented when required by competent authorities and when data allows for subcategorization.

4. While the classification criteria allowing for subcategorization is defined in the GHS for each applicable hazard class and category, there is no consistency in the way these subordinate categories are referred to. When addressing subcategorization, the GHS text refers both to categories and subcategories, indistinctly to refer to subcategorization results. This inconsistency may create confusion among regulators and users in different jurisdictions when implementing GHS through legal instruments.

II. The concept of subcategorization in the GHS

5. The GHS defines “hazard class” and “hazard category” in chapter 1.2, as follows:

*“****Hazard class*** *means the nature of the physical, health or environmental hazard, e.g. flammable solid, carcinogen, oral acute toxicity:”*

*“****Hazard category*** *means the division of criteria within each hazard class, e.g.: oral acute toxicity includes five hazard categories and flammable liquids includes four hazard categories. These categories compare hazard severity within a hazard class and should not be taken as a comparison of hazard categories more generally;”.*

6. The concept of subcategorization is introduced for the first time in the GHS in paragraph 1.1.3.1.5.4 (b) in relation to the guidance on implementation of the building block approach, as follows:

*“(b) Within a hazard class, each hazard category can be seen as a building block:*

*For a given hazard class, competent authorities have the possibility not to apply all categories. Nevertheless, in order to preserve consistency, some restrictions to this principle should be set, as follows:*

*(i) The classification criteria such as the cut-off values or concentration limits for adopted hazard categories should not be altered. However,* ***adjacent sub-categories*** *(e.g. carcinogenicity* ***categories 1A and 1B****) may be merged into one category. Nevertheless,* ***adjacent hazard categories*** *should not be merged if it results in renumbering the remaining hazard categories. Furthermore, where* ***sub-categories*** *are merged, the names or numbers of the* ***original GHS******sub-categories*** *should be retained (e.g. carcinogenicity* ***category 1 or 1A/B****) to facilitate hazard communication;*

*(ii) Where a competent authority adopts a hazard category, it should also adopt all the categories for higher hazard levels in that class. As a consequence, when a competent authority adopts a hazard class, it will always adopt at least the highest hazard category (category 1), and, where more than one hazard category is adopted, these hazard categories will form an unbroken sequence.*

***NOTE 1:*** *Some hazard classes contain additional categories that can be considered on a stand-alone basis, for example, Category 3 “transient target organ effects” for the hazard class “Specific target organ toxicity” (chapter 3.8), and hazard category “Effects on or via lactation” for the hazard class “reproductive toxicity” (chapter 3.7).*

***NOTE 2:****It is noted, however, that the goal of the GHS is to achieve worldwide harmonization (see 1.1.2.3). Therefore, while differences between sectors may persist, the use of an* ***identical set of categories*** *at a worldwide level within each sector should be encouraged.”.”.*

7. As highlighted in bold in subparagraph (b) (i) above, and in the absence of a definition, subcategorization outputs are indistinguishable referred to as “categories” and “subcategories”. This inconsistency is maintained throughout the GHS.

8. A summary of hazards classes for which subcategorization within a hazard category is possible is shown in table 1, together with the terminology used in the GHS.

**Table 1: Terminology referring to subcategorization in the GHS**

|  | *Current reference* | *GHS chapter (hazard class)* | |
| --- | --- | --- | --- |
|  |  |  |  |
| 1A, 1B, 1C 2A, 2B, 2C | Subcategory(ies) | Chapter 2.1 (Explosives) Chapter 3.2 (Skin corrosion/irritation) Chapter 3.4 (Respiratory/skin sensitization)\* | |
| 1A, 1B, 1C 2A, 2B, 2C | Category(ies) | Chapter 2.2 (Flammable gases) Chapter 3.3 (Serious eye damage/eye irritation) Chapter 3.4 (Respiratory/skin sensitization)\* Chapter 3.5 (Germ cell mutagenicity) Chapter 3.6 (Carcinogenicity) Chapter 3.7 (Reproductive toxicity) | |

\* *see also informal document INF.7.*

9. Summing up (with the exception of hazards classes mirroring the transport terminology, i.e: organic peroxides and self-reactive substances, that refer to “types” instead of categories) there are currently two main approaches in the GHS to refer to subcategorization:

(a) Category(ies) 1 and 2 divided into category(ies): 1A, 1B, 1C/ 2A, 2B, 2C



(b) Category(ies) 1 and 2 divided into subcategories (1A, 1B, 1C, 2A, 2B, 2C)



10. Subcategorization for flammable gases presents an additional challenge when it comes to understanding the hierarchy behind subcategorization. For that hazard class there is no mention to an overarching category 1. Instead, the main categories for this hazard class are referred to as category 1A, 1B and 1C with 1A being additionally subdivided into three “subcategories/types” (flammable, pyrophoric and chemically unstable) of which one of them (chemically unstable gases) is further subdivided into two additional categories (category 1A and 1B), as shown in the figure below.

**Figure 1: Subcategorization for flammable gases**



11. Subcategorization for skin corrosion/irritation (chapter 3.2) is, on the contrary, clearly explained in section 3.2.2, which states that substances can be allocated to one of the three main categories (1, 2 and 3), with the possibility to further divide category 1 “*into up to three sub-categories (1A, 1B and 1C) which can be used by those authorities requiring more than one designation for corrosivity.”.* Additionally, guidance on how and when to use subcategorization is also provided as follows:

*“…substances should be classified in Category 1 where subcategorization is not required by a competent authority or where data are not sufficient for subcategorization.*

*When data are sufficient, and where required by a competent authority, substances may be classified in one of the three sub-categories 1A, 1B or 1C.”.*

12. This explanatory text is also found in chapter 3.4 for respiratory and skin sensitizers (see 3.4.2.1.1.2 and 3.4.2.2.1.2). It provides clear guidance on how to understand subcategorization and the secretariat believes that a similar text could be used, either as a general definition in chapter 1.2 to explain subcategorization in general or alternatively, to address subcategorization in the individual chapters, as applicable, for other hazard classes.

13. A harmonized approach to subcategorization would help regulators and users to understand the relationship between hazard classes and (sub)categories; avoid misunderstandings when applying the building block approach; and facilitate implementation of the GHS through legal instruments. This could be achieved by clarifying the relationship between categories and subcategories from a hierarchical point of view and by using them accordingly in the GHS.

III. Action requested

14. As a first step, the secretariat would like to invite the Sub-Committee to express a preference on the approach to be followed when addressing subcategorization in the GHS. The following options are presented as a starting point for discussion. Following the guidance provided by the Sub-Committee, proposals for amendment to the GHS will be further developed and submitted by consideration, as appropriate.

A. Option 1: hazard categories may be divided into subcategories

15. This approach is consistent with the current approach for subcategorization for explosives (chapter 2.1); Skin corrosion/irritation (chapter 3.2) and respiratory/skin sensitization (chapter 3.4).

16. If this option is retained, a sentence could be added in the definition of hazard category using a text similar to that currently used in chapter 3.2 for skin corrosion/irritation, as shown below.

Draft proposal

(New text is shown in **bold, underlined**; deleted text is ~~crossed-out)~~

Chapter 1.2

Add the following sentence at the end of the existing definition for hazard category:

“***Hazard category*** means the division of criteria within each hazard class, e.g.: oral acute toxicity includes five hazard categories and flammable liquids includes four hazard categories. These categories compare hazard severity within a hazard class and should not be taken as a comparison of hazard categories more generally. **Subcategorization within a hazard category is available for some hazard classes and categories, when data are sufficient and where required by a competent authority. When applicable, the criteria for classification into the available subcategories (e.g. 1A, 1B, 1C, 2A, 2B) are provided in the individual chapters for the relevant hazard classes and categories.**

Insert the following reference in the alphabetical order:

***“Subcategory See “hazard category”***

***Consequential amendments***

In chapters 3.3 (Serious eye damage/eye irritation), 3.5 (Germ cell mutagenicity); chapter 3.6 (Carcinogenicity); and 3.7 (Reproductive toxicity)

* replace all references to “categories” 1A, 1B, 1C, 2A, 2B with “subcategories” 1A, 1B, 1C, 2A, 2B, as appropriate.

If option 1 is retained, the Sub-Committee may wish to consider:

- whether there is a need to add a text similar to the one currently on section 3.2.2 (for skin corrosion/irritation) and 3.4.2 (for respiratory and skin sensitizers) as indicated in paragraphs 11 and 12 above, at the appropriate place at the beginning of the chapter for the hazard classes listed; and

- consequential amendments to the proposed text for chapter 3.4 in document ST/SG/AC.10/C.4/2024/10 (see informal document INF.7).

B. Option 2: hazard categories divided into further categories

17. This approach is consistent with current subcategorization for explosives (chapter 2.1); Skin corrosion/irritation (chapter 3.2) and respiratory/skin sensitization (chapter 3.4).

Draft proposal

(New text is shown in **bold, underlined**; deleted text is ~~crossed-out)~~

Chapter 1.2

Add the following sentence at the end of the existing definition for hazard category:

“***Hazard category*** means the division of criteria within each hazard class, e.g.: oral acute toxicity includes five hazard categories and flammable liquids includes four hazard categories. These categories compare hazard severity within a hazard class and should not be taken as a comparison of hazard categories more generally. **Subcategorization within a hazard category is available for some hazard classes and categories, when data are sufficient and where required by a competent authority. When applicable, the criteria for classification into the available categories (e.g. 1A, 1B, 1C, 2A, 2B) are provided in the individual chapters for the relevant hazard classes and categories.**

***Consequential amendment***

Replace all references to “sub-categories” 1A, 1B, 1C, 2A, 2B with “categories” 1A, 1B, 1C, 2A, 2B, as appropriate.