

## **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**

**22 June 2018**

### **Thirty-fifth session**

Geneva, 4-6 July 2018

Item 3 (e) of the provisional agenda

**Classification criteria and related hazard communication:  
practical classification issues**

## **Update on the work of the informal correspondence group on Practical Classification Issues**

**Transmitted by the expert from the United States of America on behalf  
of the informal correspondence group on Practical Classification Issues**

### **Purpose**

1. The purpose of this document is to provide an update on the work undertaken by the Informal Correspondence Group on Practical Classification Issues (PCI).

### **Background**

2. At its 32nd session, the Sub-Committee approved the program of work to be undertaken by the practical classification issues informal correspondence group for the current biennium (UN/SCEGHS/32/INF.39).
3. This document presents a proposal that was the basis of discussions by the PCI working group during the 33<sup>rd</sup> and 34<sup>th</sup> Sessions. The group has reached agreement on following issue and the proposed editorial amendments to the GHS are provided in the Annex below.

### **Next steps**

4. Pending feedback from this document, the PCI group plans to submit a working paper for the 36<sup>th</sup> Session.

## Annex

### PCI Item (b):

Consider developing an example(s) to illustrate how to interpret both single exposure and repeated exposure data when interpreting the statements in Chapter 3.8 Specific Target Organ Toxicity – Single Exposure (GHS paragraph 3.8.1.6) and Chapter 3.9 Specific Target Organ Toxicity – Repeated Exposure (GHS paragraph 3.9.1.6) that effects covered in other health hazard chapters are not included in Chapters 3.8 and 3.9. In addition, the PCI will consider if further editorial updates to the GHS text are appropriate.

## Chapter 3.8 STOT- Single Exposure

### 3.8.1 Definitions and general considerations

3.8.1.1 *Specific target organ toxicity – single exposure* refers to specific, non-lethal toxic effects on target organs occurring after a single exposure to a substance or mixture. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in chapters 3.1 to 3.7 and 3.10 are included (see also para. 3.8.1.6).

3.8.1.6 Specific target organ toxicity following a repeated exposure is classified in the GHS as described in Specific target organ toxicity – Repeated exposure (Chapter 3.9) and is therefore excluded from the present chapter. Substances and mixtures should be classified for single and repeated dose toxicity independently. ~~Other specific toxic effects, listed below are assessed separately in the GHS and consequently are not included here:~~

- (a) — acute toxicity (Chapter 3.1);
- (b) — skin corrosion/irritation (Chapter 3.2);
- (c) — serious eye damage/eye irritation (Chapter 3.3);
- (d) — respiratory or skin sensitization (Chapter 3.4);
- (e) — germ cell mutagenicity (Chapter 3.5);
- (f) — carcinogenicity (Chapter 3.6);
- (g) — reproductive toxicity (Chapter 3.7); and
- (h) — aspiration toxicity (Chapter 3.10).

Other specific toxic effects, such as acute toxicity, serious eye damage/eye irritation, skin corrosion/irritation, respiratory or skin sensitization, carcinogenicity, germ cell mutagenicity, reproductive toxicity and aspiration toxicity are assessed separately in the GHS and consequently are not included here.

### 3.8.3 Classification criteria for mixtures

3.8.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, ~~mixtures may be classified for specific target organ toxicity following single exposure, repeated exposure, or both.~~ mixtures should be classified for single and repeated dose toxicity (Chapter 3.9) independently.

3.8.3.4.1 Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture will be classified as a specific target organ toxicant (specific organ specified), following ~~single exposure, repeated exposure, or both~~ when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant- single exposure and is present at or above the appropriate cut-off value/concentration limit as mentioned in Table 3.8.2 below for Category 1 and 2 respectively.

3.8.3.4.2 ~~These cut off values and consequent classifications should be applied equally and appropriately independently to both single and repeated dose target organ toxicants.~~

3.8.3.4.3 ~~Mixtures should be classified for either or both single and repeated dose toxicity independently.~~

[Note: The numbering of subsequent paragraphs will need to be adjusted appropriately]

## Chapter 3.9 STOT - Repeated Exposure

### 3.9.1 Definitions and general considerations

3.9.1.1 *Specific target organ toxicity-repeated exposure* refers to specific toxic effects on target organs occurring after repeated exposure to a substance or mixture. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in chapters 3.1 to 3.7 and 3.10 are included (see also para. 3.9.1.6).

3.9.1.6 Non-lethal toxic effects observed after a single-event exposure are classified in the GHS as described in Specific target organ toxicity – Single exposure (Chapter 3.8) and are therefore excluded from the present chapter. Substances and mixtures should be classified for single and repeated dose toxicity independently. Other specific toxic effects, such as acute toxicity, serious eye damage/eye irritation, skin corrosion/irritation, respiratory or skin sensitization, carcinogenicity, germ cell mutagenicity, reproductive toxicity and aspiration toxicity are assessed separately in the GHS and consequently are not included here.

### 3.9.3 Classification criteria for mixtures

3.9.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, ~~mixtures may be classified for specific target organ toxicity following single exposure, repeated exposure, or both.~~ mixtures should be classified for single (Chapter 3.8) and repeated dose toxicity independently.

3.9.3.4.1 Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture will be classified as a specific target organ toxicant (specific organ specified), following ~~single exposure, repeated exposure, or both~~ when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant ~~–repeated exposure~~ and is present at or above the appropriate cut-off value/concentration limit as mentioned in Table 3.9.2 below for Category 1 and 2 respectively.

3.9.3.4.2 ~~These cut off values and consequent classifications should be applied equally and appropriately independently to both single and repeated dose target organ toxicants.~~

3.9.3.4.3 ~~Mixtures should be classified for either or both single and repeated dose toxicity independently.~~

[Note: The numbering of the subsequent paragraphs will need to be adjusted appropriately]