Proposal for the ongoing 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

Purpose

1. The purpose of this paper is to present a proposal for the ongoing work of the informal correspondence group on practical classification issues.

Proposal for ongoing work

2. The following work items below are proposed by the correspondence group for the next biennium. Items (a) through (c) are carryover items from the last biennium where work is in progress. Items (d) through (j) are items that are new.

(a) Review the definitions in each of the health hazard chapters for consistency in the way the definitions are provided. For example, some definitions are taken directly from OECD test guidelines while others are more general (i.e., they don’t refer to specific tests).

(b) During the process of developing examples illustrating the application of the Interpolation within one hazard category, a question/potential new interpretation was raised. The PCI group will determine if the interpolation within one hazard category bridging principle includes an additivity approach for Chapters 3.2 and 3.3. If it does then the PCI will develop an example to illustrate how additivity of the “toxicologically active ingredients” would be applied and consider if an update to the bridging principle text is necessary.

(c) Review various terms such as Unknown or Variable compositions, Complex reaction products and Biological materials (UVCBs), complex substance, and complex mixture to determine if GHS definitions are needed. If so, then also consider any consequential or conforming changes if necessary.

(d) Propose an editorial revision to the last sentence in GHS paragraph 3.1.2.3, which provides guidance on the use of data when evaluating acute toxicity “in several animal species”. Currently, reference to effect in humans is only contained in a footnote (g) to Table 3.1.1 and with many competent authorities not selecting
Category 5 the human reference has been lost in implementing regulations. The goal of the proposed editorial revision is to make clear that both data from animal tests and human epidemiological studies should be considered.

(e) 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 updates to the GHS text is appropriate.

(f) Improve consistency in the use of terminology for hazard classes, categories and sub-categories.

(g) Propose updating Table 3.1.1 to express acute toxicity values as a range. For example, acute toxicity values for acute oral toxicity Category 3 would be expressed as >50 and ≤ 300 or 50 < ATE ≤ 300.

(h) Review the information in Table 1.5.1 for aspiration hazard Category 1 and Category 2 and determine if an update is necessary.

(i) Propose updating the reference to the European Union Safety Data Sheet Directive 91/155/EEC in paragraph 1.5.3.3.3 since the EU Directive 91/155/EEC has been repealed and replaced by Annex II of Regulation (EC) No 1907/2006 (REACH).

(j) Consider the need for hazard communication associated with the hazards of flammable vapors created in the headspace (the unfilled space left above the contents in a sealed container) for solid and liquid substances or mixtures.

Conclusion

3. The correspondence group proposes these items for the next biennium and welcomes discussion by the Sub-Committee regarding this work.