

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

6 December 2022

Forty-third session

Geneva, 7-9 December 2022

Item 7 of the provisional agenda

Programme of work for the biennium 2023–2024

Addendum to ST/SG/AC.10/C.4/2022/18 - unaddressed hazard classes: Updated terms of reference and workplan

**Transmitted by the European Union and the expert from the United States
of America**

1. During joint discussions on the proposals in ST/SG/AC.10/C.4/2022/18, it was noted that providing a more detailed terms of reference for the work would provide greater clarity on the scope of the work along with facilitating constructive processes for setting priorities by the working group. Also, improving the common understanding on the scope and deliverables will allow the group to focus on technical issues and drive its discussions towards a common understanding on how new hazards can be included in the GHS.

2. Accordingly, this document provides an updated terms of reference (ToR) proposal that provides more structure regarding the scope of the work and outlines a stepwise approach to maintaining consistency with existing hazards and hazard classes addressed in the GHS. It also recognizes that the informal working group should seek approval of the GHS Sub-Committee regarding its priority for addressing the hazards, the development of mandates to the OECD and any proposals that would alter the criteria or hazard communication elements of existing hazard classes. Based on the updated ToR, this paper also proposes a simplified short-term workplan for approval by the Sub-Committee.

Terms of reference

3. The following terms of reference are proposed recognizing that the informal working group will work in a stepwise fashion, taking into consideration that a single approach may not be appropriate for all new hazards referenced in ST/SG/AC.10/C.4/2022/18:

(a) Priority setting

Recognizing that the work will span more than 1 biennium, the informal working group will develop a workplan each biennium that identifies the hazards being addressed by the working group. Based on the state of the science for each hazard, the informal working group will propose appropriate work items (e.g., reviewing the state of the science, developing mandates to the OECD, developing classification criteria and proposal for the inclusion of a new hazard into the GHS).

(b) Development of OECD mandates for GHS Sub-Committee approval

For each hazard, the informal working group will discuss and agree on the best approach to engaging the OECD taking into consideration that the state of the science will guide the specific a mandate for the OECD. For example, it may be appropriate to ask the OECD to review and advise on the science for a particular hazard, if

necessary, before asking the OECD to develop classification criteria. In the event the informal working group agrees that the state of the science is sufficient to develop classification criteria it could move forward to complete that task, keeping in mind the informal working group must engage the OECD for a review of the proposed classification criteria prior to submitting proposals to the GHS Sub-committee.

- (c) Placement of a new hazard and criteria into the GHS
- (i) The working group should consider the best approach to incorporating a new hazard into the Purple Book taking into consideration previous approaches and the implications the proposed changes will have on existing GHS implementations. For example, if the new hazard is a differentiation of an existing hazard class then it should be included in an existing chapter (e.g., Effects on or via lactation is a separate category within the hazard class Reproductive Toxicity). In the case a new hazard class is warranted, consideration should be given if it should be addressed in a separate chapter (e.g., Desensitized Explosives) or as an addition to an existing chapter (e.g., the hazard class Chemicals under pressure was added to the existing chapter covering Aerosols).
 - (ii) In the case, a new chapter is proposed or a new hazard class is added to an existing chapter, the structure of the health hazards and Hazardous to the Aquatic Environment chapters should be used as a guide. The referenced chapters address the following sub-sections:
 - a. Definition and general considerations,
 - b. Criteria for substances
 - c. Criteria for mixtures (See 1.3.2.3)
 - i. Test data for the complete mixture
 - ii. Bridging principles
 - iii. Classification based on ingredients of the mixture
 - d. Hazard communication
 - e. Decision logics and guidance
 - (iii) In the case an update to an existing chapter is proposed and it is a differentiation of an existing classification then it would be expected that the existing classification and hazard communication elements would not be modified without consultation and agreement of the Sub-Committee. In these cases, it would be expected that the any new hazard communication element(s) (i.e., hazard and precautionary statements) would supplement the existing hazard communication elements.
 - (iv) As new hazards and/or hazard classes are added to the GHS, the working group should consider if conforming changes are needed to other sections of the GHS.
- (d) Classification criteria
- Taking into consideration the best available science the working group will:
- (i) For each hazard, agree on the best approach for classification recognizing that the GHS currently uses the following approaches:
 - (ii) Weight of evidence (WoE)
 - (iii) Substance classification in a tiered approach
 - (iv) One-step criterion-based process that involves two interrelated determinations: evaluation of strength of evidence and weight of evidence (e.g., Carcinogenicity).
 - (v) Ensure classification criteria are developed for all appropriate data sources (i.e., data from human evidence, animal studies and non-animal methods).

Workplan

4. The initial tasks of the working group for the forty-fourth session (July 2023) will be to:
 - (a) Develop a mandate to the OECD on the science needed to identify endocrine disruptors for Sub-Committee approval.
 - (b) As outlined in the ToR, the working group will determine its priorities and further develop an agreed 2023-2024 workplan for Sub-Committee approval.

Proposal

5. The Sub-Committee is invited to adopt the updated terms of reference and workplan for the informal working group on unaddressed hazards.
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