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

1 December 2023

Forty-fifth session

Geneva, 6-8 December 2023 Item 2 (e) of the provisional agenda

Work on the Globally Harmonized System of Classification and Labelling of Chemicals: Potential hazard issues and their presentation in the Globally Harmonized System

Clarification of the proposal on the inclusion of endocrine disruptors in the GHS hazard classification

Transmitted by the European Union

Background

- 1. In the document INF. 15 (forty-fifth session), the expert from China suggests to the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemical (GHS Sub-Committee) reconsidering the inclusion of endocrine disruptors (EDs) as a hazard class in the GHS.
- 2. This document clarifies the 2023-2024 PHI-IWG workplan on the inclusion of EDs in the GHS.

The workstream on endocrine disruptors

- 3. During its forty-third session in December 2022, the Sub-Committee decided 1 to include a new item on its programme of work for the biennium 2023-2024: "potential hazard issues and their presentation in GHS". The European Union volunteered to coordinate an informal working group to address this topic (PHI-IWG) based on informal document INF.39 (forty-third session) 2 updated terms of reference (ToR), in combination with document ST/SG/AC.10/C.4/2022/183. These documents define the tasks to undertake for all potential hazard issues, including substances and mixtures with endocrine disrupting properties.
- 4. At its forty-fourth session, the Sub-Committee approved the 2023-2024 workplan of the PHI-IWG presented in INF.19 (forty-fourth session), specifying the following on EDs:
 - (a) Mandate the OECD to review the science needed for classification and labelling of substances and mixtures that have endocrine disrupting properties as presented in <u>ST/SG/AC.10/C.4/2023/6</u>. This entails:
 - (i) Identify any gaps regarding the possibility to adequately classify and label under the GHS substances and mixtures that have endocrine disrupting properties for human health and/or for the environment;

¹ Report of the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals on its forty-third session (ST/SG/AC.10/C.4/86, paragraph 53)

² Addendum to ST/SG/AC.10/C.4/2022/18 - unaddressed hazard classes: Updated terms of reference and workplan

Proposal for new work on unaddressed hazard classes in the programme of work for the biennium 2023-2024

- (ii) Start with knowledge of EATS endocrine pathways and then consider other endocrine pathways for which available methods and scientific knowledge may not be as advanced⁴;
- (iii) Following the review of gaps, assess whether the existing definition of endocrine disruptors as defined by the WHO/IPCS (2002) is sufficient in the context of the GHS and, if warranted, provide recommendations to the GHS Sub-Committee for adapting the 2002 definition for application under the GHS.
- 5. Based on the report from OECD on the above, the PHI-IWG will discuss the next steps as per sub-paragraph 3 (c) of its ToR⁵ and propose recommendations to the GHS Sub-Committee on how to best proceed taking into consideration previous approaches and the implications the proposed changes will have on existing GHS implementations.
 - (a) For example, if it 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 withing the hazard class Reproductive Toxicity).
 - (b) In the event a new hazard class is warranted, consideration should be given to whether it should be addressed in a separate chapter (as it was done when the hazard class "Desensitized Explosives" was added to the GHS) or as an addition to an existing chapter (as was done when the hazard class "Chemicals under pressure" was added to the existing chapter covering "Aerosols"). If new hazards and/or hazard classes are added to the GHS, the PHI-IWG should consider whether conforming changes are needed to other sections of the GHS.
- 6. On classification criteria, taking into consideration the best available science the working group will agree on the best approach for classification recognizing that the GHS currently uses the following approaches:
 - (a) Weight of evidence (WoE)
 - (b) Substance classification in a tiered approach
 - (c) One-step criterion-based process that involves two interrelated determinations: evaluation of strength of evidence and weight of evidence (e.g., Carcinogenicity).
 - (d) Ensure classification criteria are developed for all appropriate data sources (i.e., data from human evidence, animal studies and non-animal methods).

Conclusion

7. The Sub-Committee is invited to take note of this clarification when addressing the proposal in INF.15 (forty-fifth session) on reconsidering the inclusion of endocrine disruptor in the GHS.

2

⁴ Under this task, OECD should use the existing scientific knowledge available, for example OECD Guidance Document 150, WHO/UNEP 2013 "State of the Science of Endocrine Disputing Chemicals" and WHO/IPCS (2002). OECD could also consider in this gap analysis, existing national or regional schemes for identifying endocrine disruptors, including those identified in the 2017 overview report (III) published by the United Nations Environment Programme (UNEP).

⁵ https://unece.org/sites/default/files/2022-12/ST-SG-AC10-C4-86e 0.pdf