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

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

OECD activities to support the mandate on endocrine disruptors from the GHS Sub-Committee to OECD

Transmitted by the Organisation of Economic Co-operation and Development (OECD)

Background

- 1. At its 43rd session in December 2022, the Sub-Committee agreed to include a new item on its programme of work for the biennium 2023- 2024: "potential hazard issues and their presentation in the GHS". The European Union volunteered to coordinate an informal working group to address this topic (PHI-IWG) based on the workplan and terms of reference (ToR) in ST/SG/AC.10/C.4/2022/18¹ as amended in informal document INF.39 (forty-third session)², as agreed by the Sub-Committee³.
- 2. At the 44th session in July 2023, the GHS Sub-Committee generally supported a mandate for OECD to undertake a gap analysis in current GHS hazard classes regarding the identification of endocrine disruptors (EDs). The mandate was presented by the European Commission at the PHI-IWG and was described in paragraph 12 of document ST/SG/AC.10/C.4/2023/6 and the 2023-2024 workplan for the PHI-IWG in paragraphs 15 to 19 of informal document INF.19⁴. Ithas also been added to the OECD programme of work.
- 3. The continuation of the work on endocrine disruptors in accordance with the workplan adopted at the 44th session was fully supported by the Sub-Committee at its 45th session⁵ on the understanding that the questions raised in informal document INF.15⁶ would be addressed as part of the mandate given to OECD and the ongoing work within the informal working group on the "potential hazard issues and their presentation in the GHS".

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

² See informal document INF.39 (forty-third session), paragraph 4 https://unece.org/transport/documents/2022/12/informal-documents/addendumstsgac10c4202218-unaddressed-hazard-classes

³ Report of the Sub-Committee on its forty-third session (ST/SG/AC.10/C.4/86, paragraphs 51 to 53 and Annex I)

See informal document INF.19 (forty-fourth session), paragraphs 15-19 https://unece.org/transport/documents/2023/07/informal-documents/potential-hazard-issues-and-their-presentation-0

⁵ See section II.E.2, https://unece.org/sites/default/files/2024-03/ST-SG-AC10-C4-90E.pdf

⁶ Proposal to reconsider the inclusion of endocrine disruptor in the GHS hazard classification, https://unece.org/sites/default/files/2023-11/UN-SCEGHS-45-INF15e.pdf

OECD activities to support the mandate

- 4. An *ad hoc* expert group of 55 members, as well as an additional group of another 55 experts who are kept informed of these activities, has been established. This group has been co-chaired by an expert on ED effects on human health (Joint Research Centre of the European Commission) and an expert on ecotoxicology (Swiss Federal Institute of the Environment).
- 5. The *ad hoc* group has met eight times via teleconference, including four times in 2024. The initial work focused on clarifying the mandate and agreeing to a timeline for the work. The focus of the teleconferences on the first quarter of 2024 was to walk through additional examples of how EDs are identified in various jurisdictions. The first step in the mandate to the group was to consider if there are gaps in the current GHS with regard to the ability to identify chemicals as EDs according to the WHO/IPCS definition; i.e. identify substances that are active through an endocrine mechanism that can be plausibly linked to an adverse effect. As a result of the information presented and discussions that took place during teleconferences in 2023 and on the first quarter of 2024, the OECD *ad hoc* expert group agreed that the GHS refers to adverse effect(s) on an individual or population, and do not communicate or require an investigation of the underlying mechanism (with the exception of mutagenicity). Therefore, it concluded that it would be impossible to identify EDs (based on the WHO definition) in current hazard classes and that there is a clear gap.
- 6. Currently, the OECD is assessing and identifying the gaps in relation to the identification of endocrine disrupters for human health and environmental endpoints, and identifying methods to address the gaps. During the teleconferences held on the second quarter of 2024, the OECD group discussed proposed approaches for literature searches to review methods to identify EDs acting via Estrogen, Androgen, Thyroid, Steroidogenesis (EATS) and non-EATS pathways for human health and ecotoxicology. Due to resource limitations, there is a need to agree to the scope of these undertakings. The review of methods relevant to human health will focus on endocrine pathways (EATS and non-EATS) which are known to be involved in health outcomes and will prioritize adverse effects that are known to impact public health. The review of methods relevant to environmental EDs (EATS and non-EATS) will focus on aquatic vertebrates and for regulatory purposes, population relevance of adversity must be demonstrated.
- 7. The OECD *ad hoc* expert group supported both of the work plans presented. It also agreed that for both human health and environmental EDs, it is expected that the identification of available methods for non-EATS pathways will be more difficult, as less knowledge and information are available. The outcome of this discussion will be presented to the UN GHS Sub-Committee at its 47th session scheduled in December 2024.
- 8. Results of the respective literature searches are expected to be available on the second quarter of 2024. This work will form the basis of the OECD expert group discussion on the state of the science of methods to identify EDs under the GHS in the third quarter of 2024.

Timeline

9. The OECD Secretariat presented a proposed timeline (Figure 1) for progressing with the activities detailed in the mandate from the GHS Sub-Committee. While progress will be reported at each GHS Sub-Committee session, there may be a need to continue aspects of these activities beyond the current 2023-2024 biennium. The timeline of allocated activities is as follows:

July to September 2024

- Present the progress of the work to the Sub-Committee;
- Continue meetings of the OECD *ad hoc* group via teleconference and propose options/recommendations based on the review completed at that point;
- Prepare a working document describing the work done to date on the gap analysis of current GHS hazard classes, the state of science for EATS and non-EATS modalities and the adequacy of the current WHO/IPCS definition of EDs;

October to December 2024

• Present to the Sub-Committee the work done on the gap analysis of current GHS hazard classes, on the state of science and on the WHO/IPCS definition.

Figure 1: Provisional timeline for OECD activities to support the mandate on endocrine disruptors (EDs) from the GHS Sub-Committee to OECD

