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## 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

#### Forty-fourth session

Geneva, 10-12 July 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

### Potential hazard issues and their presentation in the Globally Harmonized System: Mandate to the Organisation for Economic Co-operation and Development (OECD) on endocrine disruptors

Transmitted by the European Union on behalf of the informal working  
group on potential hazard issues and their presentation in the Globally  
Harmonized System\*

## Background

1. During its forty-third session in December 2022, the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemical (GHS Sub-Committee) decided<sup>1</sup> to include a new item on its programme of work for the biennium 2023-2024: the creation of an informal working group, coordinated by the European Union, on potential hazard issues and their presentation in GHS (PHI-IWG) based on informal document INF.39<sup>2</sup> updated terms of reference (ToR), in combination with document ST/SG/AC.10/C.4/2022/18<sup>3</sup>.
2. These documents define the PHI-IWG terms of reference for all potential hazard issues with endocrine disruptors (ED) and with persistent, bioaccumulative, toxic (PBT),

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\* A/77/6 (Sect. 20), table 20.6.

<sup>1</sup> 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](#))

<sup>2</sup> [Addendum to ST/SG/AC.10/C.4/2022/18 - unaddressed hazard classes: Updated terms of reference and workplan](#)

<sup>3</sup> [Proposal for new work on unaddressed hazard classes in the programme of work for the biennium 2023-2024](#)



very persistent, very bioaccumulative (vPvB), persistent, mobile, toxic (PMT) and very persistent, very mobile (vPvM) chemicals as follows:

- (a) Priority setting;
  - (b) Development of OECD mandates for GHS Sub-Committee approval;
  - (c) Placement of a new hazard and criteria into the GHS;
  - (d) Classification criteria.
3. The documents also define the initial tasks of the PHI-IWG ahead of the July 2023 session of the GHS Sub-Committee<sup>4</sup>. These are:
- (a) To develop, for GHS Sub-Committee approval, a mandate to OECD on the science needed to identify EDs; and
  - (b) To determine its priorities and further develop an agreed 2023-2024 workplan for GHS Sub-Committee approval.
4. This document presents a proposal on a mandate to OECD, for approval by the GHS Sub-Committee in line with sub-paragraph 3 (a).
5. In the implementation of this proposed mandate, the participation of OECD members in the PHI-IWG is encouraged. Similarly, participation of PHI-IWG members in the OECD group who will be responsible for the implementation of the proposed mandate is also encouraged. This would allow a smooth and continuous information exchange between all interested parties.
6. Based on the report of the OECD work under paragraph 12 below of the proposed mandate, the PHI-IWG will discuss the next steps.

## **Information to support the proposed mandate**

7. Over the last 30 years, an increasing body of scientific research has focused on the endocrine disrupting properties of chemicals. The resulting knowledge identifies endocrine disruptors as a concern to public and wildlife health<sup>5</sup>. The increasing incidence of many endocrine-related disorders in humans have important parallels in some wildlife populations.
8. Currently, endocrine disruptors may not be identified within existing GHS hazard classes. There is concern that this limits the ability of users of chemicals to adopt suitable risk management measures. OECD, as the focal point for GHS on health and environmental hazards, could be tasked with reviewing existing GHS hazard classes to identify any possible gaps.
9. However, for some endocrine pathways, available science may not be as advanced as the knowledge on the estrogen, androgen, thyroid and steroidogenic (EATS) pathways. Therefore, it is proposed that OECD reviews the knowledge on the EATS pathways and then consider other endocrine pathways for which available methods and scientific knowledge may not be as advanced.
10. It is proposed that OECD use existing knowledge available (for example, international test guidelines, such as those developed by OECD, information available from other international bodies and national or regional schemes) and link some endocrine mechanisms of action to adverse effects in both humans and the environment.
11. Furthermore, while there is general support for using the generic definition of endocrine disruptor as defined by the World Health Organization International Programme

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<sup>4</sup> See [informal document INF.39 \(forty-third session\), paragraph 4](#).

<sup>5</sup> WHO/UNEP, 2013. [State of the Science of Endocrine Disrupting Chemicals](#); Vandenberg, L. N. and Turgeon, J. L., 2021. Endocrine-Disrupting Chemicals. *Advances in Pharmacology*, 92.

of Chemical Safety (WHO/IPCS) (2002)<sup>6</sup> as a starting point for the GHS definition, there is some concern that the WHO definition may be overly broad. It may need to be adapted for application within the GHS.

## Proposed mandate to OECD

12. The GHS Sub-Committee mandates OECD to review the science needed for classification and labelling of substances and mixtures that have endocrine disrupting properties, as follows:

- (a) Review existing GHS hazard classes (e.g. carcinogenicity, reproductive toxicity, specific target organ toxicity, hazardous to the aquatic environment) that may include endocrine disruptors. The review should:
  - (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;
  - (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 advanced. Under this task, OECD should use the existing scientific knowledge available, for example OECD Guidance Document 150<sup>7</sup>, WHO/UNEP 2013 “State of the Science of Endocrine Disrupting Chemicals”<sup>8</sup> and WHO/IPCS (2002)<sup>9</sup>. 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)<sup>10</sup> published by the United Nations Environment Programme (UNEP);
- (b) 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;
- (c) Based on the report from OECD on (a) and (b) above, the PHI-IWG will discuss the next steps as per sub-paragraph 3 (c) of its terms of reference (see informal document INF.39 (forty-third session)<sup>11</sup> and propose recommendations to the GHS Sub-Committee on how to proceed. The GHS Sub-Committee could then task the OECD with a specific request on how to fill any gaps;
- (d) Report to the GHS Sub-Committee at each plenary session on the progress made in the implementation on the current mandate. The first report should include a provisional timetable;
- (e) Engage with the PHI-IWG as questions arise and progress warrants.

<sup>6</sup> [https://www.who.int/ipcs/publications/new\\_issues/endocrine\\_disruptors/en/](https://www.who.int/ipcs/publications/new_issues/endocrine_disruptors/en/) : "an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations".

<sup>7</sup> OECD, 2018. Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption

<sup>8</sup> WHO/UNEP, 2013. State of the Science of Endocrine Disrupting Chemicals

<sup>9</sup> WHO/IPCS, 2002. Global assessment on the state of the science of endocrine disruptors

<sup>10</sup> [https://wedocs.unep.org/bitstream/handle/20.500.11822/25636/edc\\_report3.pdf](https://wedocs.unep.org/bitstream/handle/20.500.11822/25636/edc_report3.pdf)

<sup>11</sup> [https://unece.org/sites/default/files/2022-12/ST-SG-AC10-C4-86e\\_0.pdf](https://unece.org/sites/default/files/2022-12/ST-SG-AC10-C4-86e_0.pdf)

## **Action requested**

13. The GHS Sub-Committee is invited to consider the proposed mandate for OECD on endocrine disruptors as presented in paragraph 12.
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