

## 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

4 July 2023

### 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: workplan 2023-2024

**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. At its forty-third 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.4/2022/18<sup>1</sup> as amended in informal document INF.39 (forty-third session)<sup>2</sup>, as agreed by the Sub-Committee<sup>3</sup>.
2. The initial tasks of the PHI-IWG ahead of the July 2023 Sub-Committee 44<sup>th</sup> session are:
  - (a) To develop a mandate to OECD on the science needed to identify endocrine disruptors (EDs) for GHS Sub-Committee approval; and
  - (b) To determine its priorities and further develop an agreed 2023-2024 workplan for Sub-Committee approval.
3. This document presents a proposal for a 2023-2024 workplan of the PHI-IWG, for approval by the Sub-Committee in line with sub-paragraph 2 (b), based on the workstreams identified by the PHI-IWG for each of the potential hazards<sup>4</sup>. The proposal captures the outcome of discussions within the PHI-IWG since its creation in January 2023.

### Information to support the proposed workplan

4. The European Union conducted a survey among PHI-IWG experts on potential hazard issues and their presentation in GHS to collect information on the following potential

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<sup>1</sup> [Proposal for new work on unaddressed hazard classes in the programme of work for the biennium 2023-2024](#)

<sup>2</sup> See informal document INF.39 (forty-third session), paragraph 4  
<https://unece.org/transport/documents/2022/12/informal-documents/addendum-stsgac10c4202218-unaddressed-hazard-classes>

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

<sup>4</sup> The completion of these workstreams could expand beyond the current biennium.

hazards: persistence, bioaccumulation, mobility (e.g. PBT/vPvB, PMT/vPvM), neurotoxicity, immunotoxicity and hazardous to the terrestrial environment<sup>5</sup>.

5. Specifically, the survey collected information for each potential hazard on the state of science, and references supporting the reply. The survey also collected opinions on the role that the OECD could play in the inclusion of each potential hazard issue in the GHS<sup>6</sup>. It also sought agreement on the suggested prioritization and a timeline for the different tasks to perform by the PHI-IWG, as well as by the OECD and how this would interact with the Sub-Committee.

6. Following the presentation of aggregated results, the PHI-IWG reflected and discussed a possible workstream, i.e. a list of tasks to carry out in the future, that would allow working towards inclusion of the above-mentioned potential hazards in the GHS, for Sub-Committee approval.

### **Persistence and bioaccumulation**

7. On persistence and bioaccumulation, the workstream could be carried out jointly. The following steps are proposed:

- (a) The PHI-IWG will undertake an analysis identifying if and how persistence and bioaccumulation are already identified and classified in the GHS taking into consideration comments submitted via the above-mentioned survey and complementary information provided during previous discussions at the Sub-Committee and supportive documents, such as INF.24 (forty-third session)<sup>7</sup>. The analysis should not only identify gaps in existing criteria but also potential room for improvement.
  - (i) Experts of the PHI-IWG would then discuss the result of this analysis. The desired outcome is a proposal, for Sub-Committee approval, on how best to incorporate persistence and bioaccumulation into the GHS using one of the approaches defined in the ToR of the PHI-IWG<sup>8</sup>.
  - (ii) In case of agreement by the Sub-Committee to develop criteria for persistence and bioaccumulation, then the PHI-IWG would develop such criteria and would submit a proposal for the Sub-Committee approval on a mandate to the OECD to validate these criteria based on paragraphs 3 (c) (ii), 3 (d) and others of INF.39 (forty-third session)<sup>9</sup>.
- (b) Finally, the PHI-IWG should consider if conforming changes are needed to other sections of the GHS.

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<sup>5</sup> Originally, the wording used was “substances toxic to terrestrial organisms”. However, the PHI-IWG agreed in changing to a wording in line with the existing one in the GHS “Hazardous to the Aquatic Environment”.

<sup>6</sup> See informal document INF.39 (forty-third session), paragraph 3  
<https://unece.org/transport/documents/2022/12/informal-documents/addendum-stsgac10c4202218-unaddressed-hazard-classes>

<sup>7</sup> See informal document INF.24 (forty-third session), paragraphs 3 to 6  
<https://unece.org/transport/documents/2022/11/informal-documents/addendum-stsgac10c4202218-unaddressed-hazards>

<sup>8</sup> See informal document INF.39 (forty-third session), paragraph 3  
<https://unece.org/transport/documents/2022/12/informal-documents/addendum-stsgac10c4202218-unaddressed-hazard-classes>

<sup>9</sup> *Idem*

## Persistence and mobility

8. On persistence and mobility, the following steps are proposed:
- (a) Discussion at the PHI-IWG level on persistence and mobility. This discussion would focus on clarifying the scope of the work (aim, expected added value, etc.), the definition of mobility in the GHS context, issues that the identification and potential classification would entail, and would also address other comments submitted during the above-mentioned survey; taking into consideration also complementary information such as INF.24 (forty-third session)<sup>10</sup>.
  - (b) Based on the outcome of such discussion, the PHI-IWG would propose for the Sub-Committee approval a mandate to the OECD on the state of science.
  - (c) According to the results of the OECD work reported back to the Sub-Committee, the PHI-IWG would recommend to the Sub-Committee on how best to incorporate persistence and mobility into the GHS using one of the approaches defined in the ToR of the PHI-IWG<sup>11</sup>.
9. Experts from Germany expressed their willingness to co-lead with the European Union the work on persistence and mobility.

## Immunotoxicity

10. On immunotoxicity, the PHI-IWG proposes the following workstream:
- (a) The PHI-IWG will undertake an analysis identifying if and how immunotoxicity is currently identified and classified in the GHS.
  - (b) Experts of the PHI-IWG would then discuss the result of this analysis taking into consideration comments submitted via the above-mentioned survey and complementary information. The analysis should not only identify gaps in existing criteria but also potential room for improvement.
  - (c) The desired outcome is a proposal, for Sub-Committee approval, on how to best incorporate immunotoxicity into the GHS using one of the approaches defined in the ToR of the PHI-IWG presented in INF.39 (forty-third session)<sup>12</sup>. This may include drafting a mandate to the OECD on further developing the state of science, developing criteria, or reviewing criteria developed by the PHI-IWG<sup>13</sup>.
  - (d) The PHI-IWG will follow-up on this work based on the Sub-Committee feedback.
11. Experts from the United States of America and the International Council of Chemical Associations (ICCA) expressed their willingness to co-lead the work on immunotoxicity with the European Union.

<sup>10</sup> See informal document INF.24 (forty-third session), in particular paragraphs 3 to 6 <https://unece.org/transport/documents/2022/11/informal-documents/addendum-stsgac10c4202218-unaddressed-hazards>

<sup>11</sup> See informal document INF.39 (forty-third session), paragraph 3 <https://unece.org/transport/documents/2022/12/informal-documents/addendum-stsgac10c4202218-unaddressed-hazard-classes>

<sup>12</sup> *Idem*

<sup>13</sup> It was suggested to undertake – if possible - the work under the existing OECD immunotoxicology group only focusing on *in vitro*.

## Neurotoxicity

12. For neurotoxicity, a similar workstream as for immunotoxicity was agreed. Therefore, the PHI-IWG proposes:

- (a) To undertake an analysis identifying if and how neurotoxicity is currently identified and classified in the GHS at the IWG level.
- (b) Then, the PHI-IWG would discuss the result of this analysis taking into consideration comments submitted via the above-mentioned survey and complementary information. The analysis should not only identify gaps in existing criteria but also potential room for improvement.
- (c) The desired outcome is a proposal, for Sub-Committee approval, on how to best incorporate neurotoxicity into the GHS using one of the approaches defined in the ToR of the PHI-IWG presented in INF.39 (forty-third session)<sup>14</sup>. This may include drafting a mandate to the OECD on further developing the state of science, developing criteria, or reviewing criteria developed by the PHI-IWG<sup>15</sup>.
- (d) The PHI-IWG will follow-up on this work based on the Sub-Committee feedback.

## Hazardous to the terrestrial environment

13. The PHI-IWG is aware that work on substances and mixtures hazardous to the terrestrial environment was discontinued after the GHS Sub-Committee's 17th session<sup>16</sup>. Due to the limited resources, it was not possible to finalise the development of a workstream on this matter. It is, therefore, proposed to submit by the next session an informal document presenting further details in a proposal using terrestrial toxicity data to complement data on substances and mixtures hazardous to the aquatic environment as well as any further approaches identified in future discussions. The document will also summarise the work done so far within the Sub-Committee and briefly present an overview of the scientific developments since the last reporting to the Sub-Committee<sup>17</sup>. Furthermore, it will present the input collected by the survey conducted among the PHI-IWG experts on the potential hazard issue.

14. The desired outcome of this document and its discussion would be to submit a proposal, for Sub-Committee approval, on how to best incorporate substances and mixtures hazardous to the terrestrial environment into the GHS potentially using one of the approaches defined in the ToR of the PHI-IWG presented in INF.39 (forty-third session).

<sup>14</sup> See informal document INF.39 (forty-third session), paragraph 3 <https://unece.org/transport/documents/2022/12/informal-documents/addendum-stsgac10c4202218-unaddressed-hazard-classes>

<sup>15</sup> It was suggested to undertake – if possible - the work under the existing OECD immunotoxicology group only focusing on *in vitro*.

<sup>16</sup> See [ST/SG/AC.10/C.4/34](#), para.67

<sup>17</sup> See [ST/SG/AC.10/C.4/10](#) (para 18 to 22) summarising discussion of [ST/SG/AC.10/C.4/2003/2](#) and [UN/SCEGHS/5/INF.19](#); paragraph 42 of [ST/SG/AC.10/C.4/14](#); [ST/SG/AC.10/C.4/16](#) (para. 59 to 63) summarising the discussion on [ST/SG/AC.10/C.4/2004/20](#); paragraph 57 of [ST/SG/AC.10/C.4/20](#); UN/SCEGHS/11/INF.13 [Progress report on the work of the expert group for the development of the classification and labelling criteria for the terrestrial environmental hazards](#); [ST/SG/AC.10/C.4/24](#) (para.12 to 15 and Annex 2) based on the discussion of UN/SCEGHS/12/INF.5 [Classification criteria for the terrestrial environment](#); paragraph 29 of [ST/SG/AC.10/C.4/26](#) and paragraph 26 of [ST/SG/AC.10/C.4/28](#); [ST/SG/AC.10/C.4/30](#) (para. 43 to 47); and paragraph 47 of [ST/SG/AC.10/C.4/34](#).

## Proposed workplan 2023-2024

15. Based on these workstreams identified, including on endocrine disruptors as presented in ST/SG/AC.10/C.4/2023/6<sup>18</sup>, PHI-IWG experts discussed their most efficient implementation, considering resource constraints, and would like to propose for Sub-Committee's approval the following tasks for the 2023-2024 biennium.

16. The PHI-IWG will discuss mobility, clarifying the scope of the work. Based on the outcome of such discussion, the PHI-IWG would propose, for Sub-Committee's approval, a mandate to the OECD on the state of science on mobility. In the meantime, the PHI-IWG will undertake an analysis identifying if and how persistence and bioaccumulation are already identified and classified in the GHS as presented in paragraph 7 (a). Then, the PHI-IWG will propose to the Sub-Committee how best to incorporate bioaccumulation, mobility and persistence in the GHS as indicated in paragraphs 7 (b) and 8 (c). Finally, the PHI-IWG should consider if conforming changes are needed to other sections of the GHS.

17. The implementation of the workstream on immunotoxicity will start in this biennium with an analysis identifying if and how immunotoxicity is currently identified and classified in the GHS. If resources allow, the PHI-IWG could also discuss the result of this analysis as presented in paragraph 10 (b).

18. Should the Sub-Committee approve the mandate to the OECD on endocrine disruptors<sup>19</sup>, the PHI-IWG will engage with the OECD based on their reporting on the progress made in the implementation on the current mandate. The PHI-IWG will also discuss the next steps developing a proposal for Sub-Committee approval on how to proceed with the inclusion of endocrine disruptors in the GHS based on the OECD work presented in paragraph 12 of document ST/SG/AC.10/C.4/2023/6<sup>20</sup>.

19. The PHI-IWG would prefer to postpone to the biennium 2025-2026 starting the work on neurotoxicity and on substances and mixtures hazardous to the terrestrial environment; unless additional resources become available at a later stage.

## Action requested

20. The Sub-Committee is invited to approve the 2023-2024 workplan of the PHI-IWG.

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<sup>18</sup> See working document ST/SG/AC.10/C.4/2023/6  
<https://unece.org/transport/documents/2023/04/working-documents/potential-hazard-issues-and-their-presentation>

<sup>19</sup> See working document ST/SG/AC.10/C.4/2023/6  
<https://unece.org/transport/documents/2023/04/working-documents/potential-hazard-issues-and-their-presentation>

<sup>20</sup> *Idem*