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

Potential hazard issues and their presentation in the Globally Harmonized System: status report on persistence and mobility

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 included a new item on "Potential hazard issues and their presentation in the GHS" in its programme of work for the biennium 2023-2024. This item is addressed by the 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 its forty-fourth session in July 2023, the Sub-Committee approved the 2023-2024 workplan for the PHI-IWG as proposed in informal document INF.19 (forty-fourth session)⁴.
- 3. This informal document informs the Sub-Committee of the progress on the "persistence and mobility" workstream in the "Potential hazard issues and their presentation in the GHS (PHI)" informal working group (IWG) since its adoption in July 2023.
- 4. The current state of the discussions in the PHI-IWG regarding the workstream on "persistence and mobility" is reflected both in this document and in ST/SG/AC.10/C.4/2024/9.

Status report of the work on persistence and mobility

5. The PHI-IWG noted that no harmonised rules and procedures on the classification of substances and mixtures for persistence, mobility, or for a combination of these properties

¹ 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/addendum-stsgac10c4202218-unaddressed-hazard-classes

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

⁴ See informal document INF.19 (forty-fourth session), paragraphs 15 to 19 <u>https://unece.org/transport/documents/2023/07/informal-documents/potential-hazard-issues-and-their-presentation-0</u>

seem to exist in the GHS. However, the current version of the GHS⁵ already contains various references to persistence, degradability, as well as to mobility in soil. Users of the substances and mixtures can be informed about these properties via section 12 on 'ecological information' of the safety data sheet under the GHS. In addition, degradability is used as a part of the classification criteria under the GHS hazard class "Hazardous to the aquatic environment".

- 6. Under the GHS hazard class "Hazardous to the aquatic environment", information on degradability is used in the classification scheme for long-term (chronic) aquatic hazard, in combination with information on acute toxicity only if adequate chronic toxicity data are not available. As this is only one of the approaches that can be used for the classification for chronic aquatic hazards, any particular classification for chronic aquatic hazards is not necessarily dependent on degradability. Consequently, classification (or absence of) for chronic aquatic hazard does not on its own inform on degradability.
- 7. The PHI-IWG noted that there are no explicit and sufficient references to "persistence" and "mobility"- either individually or in combination for the protection of water bodies (including drinking water resources, e.g. surface water, groundwater) to protect human health and the environment⁶.
- 8. During the discussion there were different views regarding the regulatory use of the combination of persistence and mobility. Some members of the PHI-IWG noted that the concept of combining persistence and mobility is not new to chemical hazard-based approaches. Others considered that their use in chemical hazard-based approaches is rather new, noting that persistence and mobility are used in chemical risk management, but there is still ongoing debate as to the scientific foundation of these concepts for use in hazard-based approaches.
- 9. The PHI-IWG therefore concluded upon the need to consult the OECD on this matter as its focal point for health and environmental hazards.

Proposed mandate to the OECD on persistence and mobility in the GHS

- 10. The PHI-IWG have submitted to the Sub-Committee a proposal to mandate to the OECD to review the state of the science needed for the classification and labelling of substances and mixtures that have persistence (P) and mobility (M) properties ⁷. It was clarified that the wording "state of the science" and "mixtures" was included for consistency with the GHS text.
- 11. The PHI-IWG discussed if the potential hazards should be assessed both individually and in combination. The proposed mandate entails a stepwise approach foreseeing a review of the state of the science as outlined in sub-paragraph 4 (a) in document ST/SG/AC.10/C.4/2024/9. The results of this work can be used for the assessment of the

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⁵ See Globally Harmonized System of Classification and Labelling of Chemicals (GHS Rev. 10, 2023) https://unece.org/transport/dangerous-goods/ghs-rev10-2023

In this context it is also relevant to note that under the hazard class "Hazardous to the aquatic environment, it is stated (Section 4.1.1.7.1) that "The aquatic environment may be considered in terms of the aquatic organisms that live in the water, and the aquatic ecosystem of which they are part. To that extent, the proposal does not address aquatic pollutants for which there may be a need to consider effects beyond the aquatic environment such as the impacts on human health etc. The basis, therefore, of the identification of hazard is the aquatic toxicity of the substance, although this may be modified by further information on the degradation and bioaccumulation behaviour".

Mandate to the Organisation for Economic Co-operation and Development (OECD) on persistence and mobility. https://unece.org/transport/documents/2024/04/working-documents/potential-hazard-issues-and-their-presentation-3

potential hazard of the combination of these properties. There is common understanding that P and M should be addressed in combination⁸ to identify problematic substances. The proposed mandate therefore includes an assessment of the potential hazard of the combination of these properties.

- 12. Some experts expressed the need to also address toxicity (PMT), as well as to address very persistent and very mobile substances (vPvM). Aware of the prioritisation as per the PHI-IWG workplan, the addition of toxicity (T) as a factor in combination with P and M has not yet been discussed within the PHI-IWG. However, following the review of persistence and mobility, the PHI-IWG may wish to consider T in combination with P and M. The PHI-IWG decided therefore that if the OECD is tasked with a specific request on how to fill any gaps, it could consider T to humans and/or to the environment as an additional intrinsic property to complement P and M.
- 13. The PHI-IWG discussed if the scope should be exclusively limited to drinking water resources or if the scope should cover an overall protection goal both for human health and the environment. This included a reflection on whether to use the terms "all" or "any" water bodies as part of the protection goal. It was noted that different water bodies may be relevant in different jurisdictions and that a review of the use of surface water for drinking water across UN regions may be helpful. It was also pointed out that the GHS already covers other hazards to the aquatic environment in a dedicated hazard class.
- 14. On the possible influence of environmental factors and the ability to generate standardized results and available testing methodologies, some members suggested that persistence and mobility are intrinsic properties, the degree of which is influenced by environmental factors. They considered that data on persistence and mobility can be generated, standardized and used to compare and classify substances.
- 15. On the other hand, other members disagreed that persistence and mobility constitute intrinsic properties, pointing out that the GHS refers to the "degree of degradation" depending as well on the actual conditions in the receiving environmental compartment, and that M is influenced by various environmental factors.
- 16. Therefore, the PHI-IWG agreed that the OECD should consider the available testing methodologies and the ability to generate standardized results as part of the mandate on persistence and mobility; clarifying if persistence and mobility can be defined as intrinsic properties under the GHS.
- 17. Some members proposed that additional work is needed to clarify and establish which are the relevant environmental factors to be considered for each property as well as their potential influence for the assessment. The establishment of these factors needs to take place in a conservative (realistic worst-case) basis and be considered when generating standardised test results.
- 18. In the context of sub-paragraph 4 (b) of the draft mandate, the PHI-IWG also discussed if the assessment should include considerations on whether there should be a new definition for substances and mixtures that are determined to be both persistent and mobile, and if so, to provide a recommendation for this. It was mentioned that in case of amended definitions, their consistency with the GHS chapter "Hazardous to the Aquatic Environment" should be investigated. Finally, in assessing the existing definitions for persistence and mobility in the GHS, the PHI-IWG would highly appreciate if the OECD could clarify the difference in meaning of "degradability" and "degree of degradation" in the current GHS.
- 19. A summary of technical points that were discussed by the PHI-IWG on the definition of persistence and on the definition of mobility were summarized in the annex to ST/SG/AC.10/C.4/2024/9. There were concerns raised by some members on the structure of the Annex and the PHI-IWG discussed different views in relation to what information to provide in the annex to document ST/SG/AC.10/C.4/2024/9. The following paragraphs

⁸ ST/SG/AC.10/C.4/86, paragraphs 52-53.

present further details of discussion points raised during the elaboration of the proposed

Proposed definitions of "persistence" and "mobility" in the GHS

General considerations

- 20. There was general support among the PHI-IWG for using the existing language in the GHS as much as possible to define persistence and mobility. The existing defining elements in the GHS for persistence and for mobility are presented in annex to document ST/SG/AC.10/C.4/2024/9. As per subparagraph 4 (b) of that document, if the OECD finds that the existing definitions for persistence and mobility in the GHS are not fit for purpose in the context of classification and labelling, the OECD could consider the technical points presented in paragraph 3 of the annex to document ST/SG/AC.10/C.4/2024/9 for recommending the adaptation or replacement of the current definitions. These technical points intentionally have some not yet agreed wording in the proposed definitions in square brackets (e.g. "[organic]", "[smaller]") for discussion by the OECD.
- 21. There was also general support among the PHI-IWG for maintaining consistency with the current structure of the GHS. In the GHS, there is typically a clear delineation between the definition, which is usually brief, and elements for the interpretation of the definition (e.g. half-life, specific test mechanisms), which are provided in further sections (e.g. basic elements, criteria).
- 22. It was also requested to point out that the PHI-IWG did not discuss the basic elements nor the criteria for persistence and mobility in the GHS so far.
- 23. It was also mentioned that it will be necessary to analyse the implications on the GHS of defining a new hazard class based on combinations of substance properties; recalling that the GHS already has examples where the combination of intrinsic properties can be used in criteria.

On the proposed definition of "persistence" in the GHS

- 24. During the discussion within the PHI-IWG, the potential influence of external conditions on persistence was highlighted and discussed, as there is ongoing scientific debate as to whether persistence is an intrinsic property. The PHI-IWG further noted the difference between "intrinsic degradability" and the "degree of degradation".
- 25. Furthermore, the PHI-IWG suggested considering degradability for each of the relevant environmental compartments, in line with existing approaches such as OECD test guidelines 307, 308 and 309. Namely, persistence needs to be considered in soil, water and sediment compartments in the GHS.
- 26. The PHI-IWG discussed the appropriateness of certain terminologies in the proposed definition of persistence. Specifically, the meanings of the terms "decomposition" and "degradation" were discussed. There was a general understanding that the difference between these terms lies within the endpoint measurement, i.e. mineralisation versus primary degradation, respectively. The PHI-IWG further discussed whether the term "degradation" or "transformation" and "primary degradation" or "biodegradation" would be more appropriate to use. Several experts acknowledged the need to assess intermediates, and to classify these in addition to end products of the degradation process. Some experts expressed caution in using the term "organic", as reflected by the square brackets, which should be further considered by OECD. Others pointed to annexes of the GHS that recognise the specificities of "metals" and "metal compounds".
- 27. Finally, the PHI-IWG discussed the value in including further references to GHS annexes in the definition of persistence. In particular, Annex 9 on the guidance on hazards to the aquatic environment and Annex 10 on the guidance on the transformation/dissolution of metals and metal compounds in aqueous environment should be considered by the OECD. These references were added in the annex to document ST/SG/AC.10/C.4/2024/9. The PHI-IWG also considered that the *Revised introduction to the OECD guidelines, section 3* is one

of the relevant documents to be considered by the PHI-IWG as well as by the OECD in the context of the workstream "persistence and mobility" ⁹.

On the proposed definition of mobility in the GHS

- 28. The PHI-IWG discussed the different pathways for the release of relevant substances into the environment, including soil, sediment and water. It was agreed that limiting the definition of mobility to soil would not reflect the current state of the science, as drinking water is not solely sourced from groundwater in all regions of the world. A wider definition, encompassing sediment, soil and water was deemed more appropriate by the PHI-IWG.
- 29. The PHI-IWG considered whether the definition of mobility also encompasses the transport of substances that are bound to particles. The conclusion of the PHI-IWG was however not to include this element in the definition of mobility.
- 30. Furthermore, the PHI-IWG proposed that the definition of mobility should relate to hydraulic transport through surface water and sub-surface environments, i.e. sediment, soil, aquifers and riverbanks; rather than long-range transport through air.
- 31. Moreover, the PHI-IWG discussed the distinctions between "transport", "sorption" and "filtration/permeation". It could be further investigated whether mobility can be quantified by measuring the sorption in the environmental matrix, including but not limited to sorption to organic matter in soil and sediments. In this context, a review of existing standardised test guidelines to assess mobility could be performed.
- 32. The suggestion of introducing a definition for the term "transport" in the GHS was mentioned. Furthermore, the suggestion that this definition could be developed in analogy to the GHS concept of "degree of degradability" was also mentioned.
- 33. On the definition of mobility proposed in sub-paragraph 3 (b) of the annex in ST/SG/AC.10/C.4/2024/9, the word "intrinsic property" in square brackets reflected that the PHI-IWG could not come to consensus. Some experts of the PHI-IWG suggested that "mobility" is an intrinsic substance property, arguing that low adsorption potential is a fundamental physico-chemical substance property (size, polarity, ionizability). Other experts suggested that the substance's mobility could not be defined as an intrinsic property due to the co-dependence on environmental factors. There was also a suggestion to use the terms "potential" of a substance and "environmental partitioning potential to the water phase" in the definition of mobility.

Actions requested from the Sub-Committee

- 34. The Sub-Committee is invited to take note of the progress of the discussions with the PHI-IWG on the workstream "persistence and mobility" as presented in paragraphs 5 to 33 above, as well as in document ST/SG/AC.10/C.4/2024/9.
- 35. The PHI-IWG supports the proposed mandate to the OECD on "persistence" and "mobility" contained in paragraph 4 of document ST/SG/AC.10/C.4/2024/9 and recommends its adoption by the Sub-Committee. The PHI-IWG recommends informing the OECD on the progress of such discussions.
- 36. The Sub-Committee is therefore invited to transmit both the mandate presented in document ST/SG/AC.10/C.4/2024/9 and this informal document to the OECD.

OECD (2006), Revised Introduction to the OECD Guidelines for Testing of Chemicals, Section 3, OECD Guidelines for the Testing of Chemicals, Section 3, OECD Publishing, Paris, https://doi.org/10.1787/9789264030213-en.