

Distr.: General 16 April 2024

Original: English

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-sixth session Geneva, 3-5 July 2024 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 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*

I. Background

1. At its forty-third session1 the Sub-Committee included an item on "potential hazard issues and their presentation in the GHS" on its 2023-2024 programme of work and welcomed the proposal from the European Union to lead an informal working group on this topic. The Sub-Committee noted that the informal working group on potential hazard issues (hereafter referred to as PHI-IWG), will work in a stepwise fashion according to the agreed terms of reference (ToR)². At its forty-fourth session³ the Sub-Committee agreed to the 2023-2024 workplan proposed by the PHI-IWG.

2. During the discussions on "persistence" and "mobility" (workstream co-led by the European Union and Germany) the PHI-IWG worked to clarify the scope of work, the definitions to refer to in the GHS context and other issues. Such discussion and comments on documents circulated within the PHI-IWG highlighted the need to consult OECD as the focal point for environmental and human health hazards.

³ See report of the Sub-Committee on its forty-fourth session (ST/SG/AC.10/C.4/88, paragraphs 17 to 19) and informal document INF.19 (forty-fourth session).



^{*} A/78/6 (Sect. 20), table 20.5.

¹ See report of the Sub-Committee on its forty-third session (ST/SG/AC.10/C.4/86, paragraph 53).

² Informal document INF.39 (forty-third session).

3. Following the outcome of this work, the PHI-IWG developed the proposal for a mandate to the OECD on the state of science of "persistence" and "mobility" contained in this document for consideration and approval by the Sub-Committee at its forty-sixth session.

II. Proposed mandate to the OECD

4. The GHS Sub-Committee mandates the OECD to review the state of the science needed for classification and labelling of substances and mixtures that have "persistence" and "mobility" properties, as follows:

(a) To review the state of the science on "persistence" and "mobility", including to assess the potential hazard of the combination of these properties particularly for substances and mixtures that may have a high potential to cause contamination of water bodies (including drinking water resources, e.g. surface water, groundwater) to protect human health and the environment. The state of the science review should:

(i) Identify any gaps regarding the possibility to adequately classify and label substances and mixtures that have "persistence" and "mobility" properties under the GHS, both individually and in combination, for the protection of human health and the environment;

(ii) Consider the possible influence of environmental factors, the ability to generate standardized results and the available testing methodologies.

(b) To assess whether the existing definitions for "persistence" and "mobility" in the GHS are fit for purpose in the context of classification and labelling and, if necessary, provide recommendations to the GHS Sub-Committee for adapting or replacing the current definitions to reflect the outcome of the state of the science review - as detailed in subparagraph 4 (a). The annex to this document provides a summary of technical points, based on discussions within the PHI-IWG, that can be considered to this end.

(c) Based on the report from the OECD on subparagraphs 4 (a) and 4 (b) above, the PHI-IWG will discuss the next steps as per its terms of reference (see subparagraph 3 (c) in INF.39 (forty-third session)) 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. For example, consideration of toxicity to humans and/or to the environment as an additional intrinsic property to complement "persistence" and "mobility".

(d) To report to the GHS Sub-Committee at each plenary session on the progress made on the implementation of the current mandate. The first report should include a provisional timetable.

(e) To engage with the PHI-IWG during the process as questions arise and progress warrants.

III. Action requested from the Sub-Committee

5. The Sub-Committee is invited to consider and approve the proposed mandate to the OECD on "persistence" and "mobility" as detailed in paragraph 4.

Annex

Definitions of persistency and mobility

1. In the GHS context, it is suggested to refer to the following definition for persistence:

(a) Persistence (P) and degradability are according to section A4.3.12.6 "the potential for the substance or the appropriate constituents of a mixture to degrade in the environment, either through biodegradation or other processes, such as oxidation or hydrolysis". Moreover, persistence (and degradability) are listed as "ecotoxicological properties (which) are substance specific" in section A4.3.12.3 and section 4.1.2.7 refers to "the intrinsic properties of a lack of rapid degradability [...] may be used to assign a substance to a long-term (chronic) hazard category". According to section 4.1.1.1, degradation means the "decomposition of organic molecules to smaller molecules and eventually to carbon dioxide, water, and salts".

(b) Furthermore, section 4.1.2.11 on rapid degradability indicates that various environmental degradation processes can be determined. Section 4.1.2.12.1 adds that biodegradability is a concept which has limited or no meaning for inorganic compounds and metals. Finally, Annex 9 states in section A9.4.1.1 that "degradability is one of the important intrinsic properties of substances that determine their potential environmental hazard (and even if) classification of substances is primarily based on their intrinsic properties [...] The degree of degradation depends not only the intrinsic recalcitrance of the molecule, but also on the actual conditions in the receiving environmental compartment. [...]". Specifically, A9.7.1.5 says "For inorganic compounds and metals, clearly the concept of degradability, as it has been considered and used for organic substances, has limited or no meaning. Rather, the substance may be transformed by normal environmental processes to either increase or decrease the bioavailability of the toxic species". On the latter, Annex 10 also provides more guidance.

2. In the GHS context, it is suggested to refer to the following definition for mobility:

(a) Currently, Annex 4 "Guidance on the preparation of safety data sheets (SDS)" in A4.3.12 section 12: "Ecological Information" only refers to mobility in soil. Section A4.3.12.8 defines mobility as "the potential of a substance [...], if released to the environment, to move under natural forces to the groundwater or to a distance from the site of release". Moreover, mobility in soil is listed as one of five "basic properties" for which data should be provided' in section A4.3.12.2. Section A4.3.12.8 further adds "Information on mobility can be determined from relevant mobility data such as adsorption studies or leaching studies. For example, K_{oc} values can be predicted from octanol/water partition coefficients (K_{ow})".

3. As in subparagraph 4 (b), if the existing definitions for "persistence" and "mobility" in the GHS are not fit for purpose in the context of classification and labelling, the following technical points, based on discussions within the PHI-IWG¹, can be considered:

(a) The definition of "persistence" could be reformulated as follows: persistence (P) is the intrinsic property of a[n organic] substance to resist degradation/transformation in the environment, either through biodegradation or other processes from one chemical species into other(s) and, eventually, to carbon dioxide, water and salts. Degradation refers to either primary degradation or mineralization to carbon dioxide, water and salts.

(b) To be more broadly applicable to chemical releases to the environment, the definition of "mobility" could be reformulated as: mobility (M) is the [intrinsic property] potential of a substance, if released to the environment, to move under natural forces to reach water bodies (including drinking water resources, e.g., surface water, groundwater), or to a distance from the site of release, as a consequence of [its low adsorption potential/environmental partitioning potential to the water phase].

¹ The text in square brackets reflects divergent views.