

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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Addendum to ST/SG/AC.10/C.4/2022/18 - unaddressed hazards: persistent, bioaccumulative, toxic (PBT); very persistent, very bioaccumulative (vPvB); persistent, mobile, toxic (PMT); and very persistent, very mobile (vPvM) substances

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1. This document provides complementary information on persistent, bioaccumulative, toxic (PBT); very persistent, very bioaccumulative (vPvB); persistent, mobile, toxic (PMT) and very persistent, very mobile (vPvM) substances in support of the proposal for new work on unaddressed hazard classes in the programme of work for the biennium 2023-2024. The new work item would initially cover these substances as well as endocrine disruptors (ED) for human health and the environment¹.

Background

2. Substances with persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB) properties do not easily break down in the environment and tend to bioaccumulate. Even at low toxicity, they have the potential to cause severe harm, because they build up, for example, in the adipose tissue of mammals, increasing their concentration over time. Once in the food chain, they magnify at each level, leading to higher concentrations in top predators and humans. Experience has shown that the accumulation of these substances in the environment is difficult to reverse, as cessation of emission does not readily result in lowering their concentration, and the effects of this accumulation are unpredictable in the long-term. In the case of vPvB substances, “*even if no toxicity is demonstrated in laboratory testing, long-term effects might be possible since high but unpredictable levels may be reached in (human or the environment over extended time periods)*”². Moreover, PBT/vPvB substances have the potential to contaminate remote pristine areas. They also pose particular challenges to the reliability of quantitative risk assessment, as a “safe” concentration in the environment cannot be established with the available methodologies³. In Europe alone, some 3.5 million sites are already contaminated by hazardous and persistent substances. Contamination of natural resources has severe economic consequences, ranging from the extremely high costs of remediation to loss of natural resources such as drinking water, land, soils and fish stocks from productive use⁴.

¹ ST/SG/AC.10/C.4/2022/18 <https://unece.org/info/Transport/Dangerous-Goods/events/368936>

² ECHA, 2017. [Guidance on Information Requirements and Chemical Safety Assessment](#). Version 3.0 – July 2017.

³ ECHA, 2017. [Guidance on the Application of the CLP Criteria. Guidance to Regulation \(EC\) No 1272/2008 on classification, labelling and packaging \(CLP\) of substances and mixtures](#). Version 5.0 – July 2017.

⁴ European Commission, 2017. [Study for the Strategy for the Non-Toxic Environment of the 7th EAP](#).

3. Those substances and mixtures with persistent and bioaccumulative properties – whether or not they are toxic - are not systematically identified and classified due to regulatory gaps⁵. Information on these properties is hence often not communicated to downstream users, limiting downstream users’ ability to make informed purchase choices and to adopt suitable risk management measures. The lack of identification criteria may also result in the failure to define risk management provisions in downstream legislation referring to hazard classification.

4. In the European Union, PBT/vPvB substances meeting the criteria set out in paragraph 1 of Annex D to the Stockholm Convention⁶ are controlled through the adoption of appropriate measures⁷. However, not all PBT/vPvB substances present such a risk that they should be eliminated (Annex A of the Stockholm Convention), or restricted (Annex B). For those substances not listed in the Stockholm Convention, identification and communication on their hazardous properties may be sufficient. Moreover, identification of PBT and vPvB substances under GHS would allow a comprehensive identification of the best candidates meeting the criteria set in Annex D of the Stockholm Convention.

5. Likewise, substances with persistent, mobile and toxic (PMT) or very persistent, very mobile (vPvM) properties do not easily break down in the environment and tend to contaminate water compartments, used as resources for drinking water. Even at low toxicity, they have the potential to cause significant harm, because they are easily lixiviated through the soil and other relevant layers, such as riverbanks. Once in water compartments, routine and affordable water treatment processes, such as potabilization or wastewater treatment barely remove those substances, which may be toxic to humans and/or to the aquatic life. Moreover, PBT/vPvB substances have the potential to contaminate remote pristine areas, due to their high mobility properties. In Europe alone, diffuse pollution impacts 33% of surface water and 34% of groundwater bodies and point source pollution affects 15% of surface and 14% of groundwater bodies⁸. At global level, 25.7% of 1052 water samples, representing more than 471 million people, contained a chemical at concentration higher than what is considered safe for aquatic organisms⁹.

6. Substances and mixtures with persistent and mobile properties – whether or not they are toxic - are not systematically identified and classified in the absence of harmonized rules¹⁰. Information on these properties is hence not communicated to downstream users, limiting downstream users’ ability to make informed purchase choices and to adopt suitable risk management measures, reducing the need for additional treatment of waste or drinking waters. The lack of identification criteria may also result in the failure to define risk management provisions in downstream legislation referring to hazard classification.

7. Furthermore, several Sustainable Development Goals (SDG) are linked to these unaddressed hazard classes:

- (a) SDG 3 Good health and well-being – Target 3.9 “By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil

⁵ In the European Union, the [REACH regulation](#) provides for such criteria for substances which are placed on the EU market above 1 ton per year. So do [the Plant protection product regulation](#) and the [Biocide product regulation](#). As other relevant substances are not covered, the EU has developed cross-cutting criteria which would apply to chemical substances and mixtures once adopted.

⁶ [Stockholm Convention on persistent organic pollutants](#) (POPs)

⁷ See art. 3(3) of European Union Regulation 2019/1021 on persistent organic pollutants <https://europa.eu/!cPVG6q> and Annex XIII of European Union Regulation 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) <https://europa.eu/!gwXTd6>

⁸ EEA, 2019. Drivers of and pressures arising from selected key water management challenges - A European overview, <https://www.eea.europa.eu/publications/drivers-of-and-pressures-arising/download>

⁹ Wilkinson et al., 2022. Pharmaceutical pollution of the world’s rivers. PNAS, vol. 119, no. 8, <https://doi.org/10.1073/pnas.2113947119>

¹⁰ There have been a lot of academic research and development in this area, notably since 1990’s, such as [Jin et al., 2020](#), [Rüdel et al., 2020](#), [Bieber et al., 2017](#), [Reemtsma et al., 2016](#), [Neumann et al., 2015](#), [Knepper et al. 1999](#).

pollution and contamination”. The inclusion of unaddressed hazard classes will contribute to this goal by better protecting human health.

(b) SDG #6 Clean water and sanitation – Target 6.3 “By 2030, improve water quality by reducing pollution, eliminating dumping and minimizing release of hazardous chemicals and materials, halving the proportion of untreated wastewater and substantially increasing recycling and safe reuse globally”.

(c) SDG #9 Industry, innovation and infrastructure – Target 9.4 “By 2030, upgrade infrastructure and retrofit industries to make them sustainable, with increased resource-use efficiency and greater adoption of clean and environmentally sound technologies and industrial processes, with all countries taking action in accordance with their respective capabilities”: the unaddressed hazard classes will help in the identification of sustainable alternatives.

(d) SDG #12 Responsible consumption and production – Target 12.4 “By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment”: the unaddressed hazard classes will have downstream consequences, which will in the end impact the full life cycle of this products.

8. There is therefore the need to further investigate on PBT/vPvB and PMT/vPvM substances as expressed during the forty-second session of the Sub-Committee. The annex to this document provides an overview on the latest state of science for these substances.

9. The European Union is currently reviewing classification criteria for these substances. Once adopted at the European Union level, such classification will be submitted for information to the Sub-Committee developing the criteria in the GHS.

Conclusion

10. Experts are invited to take note of the elements supporting the addition of unaddressed hazards: persistent, bioaccumulative, toxic (PBT); very persistent, very bioaccumulative (vPvB); persistent, mobile, toxic (PMT); and very persistent, very mobile (vPvM) substances as unaddressed hazard class in the Sub-Committee programme of work for 2023-2024.

Annex

State of science on test guidelines and test methods

1. All necessary test methods to identify PBT and vPvB, as well as PMT and vPvM substances are available, allowing Member Countries to the Stockholm Convention to submit proposals to add substances to Annexes A, B or C of this Convention. Amongst others, the following can be listed.
2. On persistence:
 - (a) [Test No. 310: Ready Biodegradability - CO₂ in sealed vessels \(Headspace Test\)](#)
 - (b) [Test No. 302C: Inherent Biodegradability: Modified MITI Test \(II\)](#)
 - (c) [Test No. 316: Phototransformation of Chemicals in Water – Direct Photolysis](#)
 - (d) [Test No. 314: Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater](#)
 - (e) [Test No. 309: Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test](#)
 - (f) [Test No. 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems](#)
 - (g) [Test No. 307: Aerobic and Anaerobic Transformation in Soil](#)
 - (h) [Test No. 306: Biodegradability in Seawater](#)
 - (i) [Test No. 302B: Inherent Biodegradability: Zahn-Wellens/ EVPA Test](#)
 - (j) [Test No. 301: Ready Biodegradability](#)
 - (k) [Test No. 304A: Inherent Biodegradability in Soil](#)
 - (l) [Test No. 302A: Inherent Biodegradability: Modified SCAS Test](#)
 - (m) [EU Regulation \(EC\) 440/2008 on laying down testing methods](#)
 - (n) US test method for the determination of aerobic aquatic biodegradation ([Title 40§796.3100](#))
3. On bioaccumulation:
 - (a) [Test No. 305: Bioaccumulation in Fish: Aqueous and Dietary Exposure](#)
 - (b) [Test No. 317: Bioaccumulation in Terrestrial Oligochaetes](#)
 - (c) [Test No. 315: Bioaccumulation in Sediment-dwelling Benthic Oligochaetes](#)
4. On mobility:
 - (a) [Test No. 312: Leaching in Soil Columns](#)
 - (b) [Test No. 123: Partition Coefficient \(1-Octanol/Water\): Slow-Stirring Method](#)
 - (c) [Test No. 121: Estimation of the Adsorption Coefficient \(K_{oc}\) on Soil and on Sewage Sludge using High Performance Liquid Chromatography \(HPLC\)](#)
 - (d) [Test No. 117: Partition Coefficient \(n-octanol/water\), HPLC Method](#)
 - (e) [Test No. 107: Partition Coefficient \(n-octanol/water\): Shake Flask Method](#)
 - (f) [Test No. 106: Adsorption -- Desorption Using a Batch Equilibrium Method](#)
 - (g) US test method for the determination of sediment and soil adsorption isotherm ([Title 40§796.2750](#)).