



**CHEMTrust**

Protecting humans and wildlife  
from harmful chemicals

**Submission**

## **CHEM Trust comments on Commission document Ad-hoc CA/03/2021 'Discussion on PMT/vPvM possible criteria in CLP'**

**Follow up to Ad Hoc Meeting of CARACAL PBT/vPvB/PMT/vPvM criteria 30 September 2021**

*October 2021*

### **General comments**

CHEM Trust welcomes the Commission proposal on PMT/vPvM criteria in CLP. The addition of these two new hazard classes will allow to fill an important regulatory gap regarding certain persistent and very persistent substances which have the potential to irreversibly accumulate in the water cycle<sup>1</sup>. Addressing the accumulation in environmental media beyond their accumulation in organisms (accounted for by the PBT/vPvB criteria) is key because it means that these substances have the potential to reach levels leading to adverse effects on human health, wildlife and ecosystems when continuously exposed to the media.

Therefore, strengthening the regulatory oversight on such substances is of primary importance to protect the quality of drinking water and reduce human exposure to potentially harmful substances<sup>2</sup>. It is also critical to protect aquatic wildlife and ecosystems by preventing the accumulation of such substances in the water environments, including freshwater and marine. Finally, it is also relevant for the protection of water resources for terrestrial wildlife and ecosystems.

We are hopeful that the adoption and implementation of fully protective PMT/vPvM criteria will allow reducing the overall burden of synthetic chemicals accumulating in natural water resources which is in agreement with the Commission zero pollution ambition for a non-toxic environment.

### **Criteria for PMT vPvM identification**

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<sup>1</sup> Hale, S. et al., 2020. Persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances pose an equivalent level of concern to persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances under REACH. Environmental Sciences Europe, 32, 155. <https://enveurope.springeropen.com/articles/10.1186/s12302-020-00440-4>

<sup>2</sup> CHEM Trust, September 2021. EU Court hearing on GenX: company Chemours challenges EU authority. <https://chemtrust.org/genx-court-hearing/>

*Question 1: Do you agree that two hazard classes - one for PMT and one for vPvM should be established?*

**CHEM Trust supports the creation of two new hazard classes, one for PMT, one for vPvM.**

### **1. Choice of the PMT/vPvM criteria**

*Question 2: Do you agree that using log Koc and Persistency is sound to identify mobile substances that can contaminate natural water resources?*

**CHEM Trust supports the use of log Koc in conjunction with Persistency to identify mobile substances with potential to accumulate in the water cycle and contaminate natural water resources.**

Firstly, persistence is the decisive property when considering substances with the potential to contaminate and accumulate in environmental compartments:

- Contamination potential: Persistent substances *'have the time'* to be transported from their source of emission to the natural environment, independently of their mode of transport.
- Accumulation potential: Continuous emission of persistent substances leads to increasing concentration of these substances in the natural environment.

Secondly, when considering the environmental behaviour of substances in the water cycle and natural water resources, their affinity for the water compartment is crucial: this means whether a substance will preferentially bind to e.g. soil, sediments, sludge or be mainly present in the water phase. This is quantified by the partition coefficient between organic carbon and water (Koc), with higher values signalling stronger sorption potential to e.g. soil, and lowest values signalling higher affinity with the water phase and therefore higher mobility potential in the aquatic environment. This intrinsic parameter has the merit to be relevant in different transport scenarios relating to the contamination of the water environment. In conjunction with P, log Koc allows to describe the ability of a substance to breakthrough bank filtration, wastewater treatment, drinking water treatment and migrate through agricultural soil.

Finally, using log Koc for the M criterion is a much more straightforward option than predicting leachability based on modelling considering a large number of external factors. It is an intrinsic parameter that is relatively straightforward to derive and that is relevant in any environmental context.

### **2. Use of PMT/vPvM criteria**

*Question 4: Do you agree with the cut-off criteria with regard to log Koc*

**CHEM Trust does not support a log Koc cut-off of <3 for M and <2 for vM. CHEM Trust supports a more protective log Koc cut-off of <4 for M and <3 for vM.**

To protect the quality of drinking water as well as aquatic environments as a whole, the accumulation of potentially harmful synthetic chemicals in the water environment should be prevented. For chemicals with an affinity for the aqueous phase, their potential to accumulate is determined by their persistency. Therefore, even chemicals with relatively high log Koc and therefore, only slightly mobile in water, will have the potential to accumulate in the water environment as long as they are persistent and continuous emissions take place (including leaching from legacy contaminated sites).

In CHEM Trust view the criteria used for the new hazard classes must be protective to avoid persistent water contaminants falling through the net. In the present case, the size of the net is defined by the log Koc threshold.

Log Koc cut-off values of <4 for M and <3 for vM are the ones proposed by UBA following extensive stakeholder consultation, rigorous scientific reasoning, and further validation by real monitoring data (Arp and Hale 2019<sup>3</sup>; Neumann and Schliebner 2019<sup>4</sup>). Highly persistent substances with the potential to reach remote areas will already be missed with these thresholds as expressed in the UBA reports.

The UBA reports state that *“The cut-off value of the assessment criterion for M (log Koc value less than 4.0) is scientifically justified for the protection against bank filtration breakthrough of substances emitted in high volumes or in close proximity to the sources of our drinking water.”* Bank filtration breakthrough is of most concern for chemicals entering the environment through wastewater such as industrial chemicals (including REACH-registered substances and unregistered vP PFASs) and pharmaceuticals. UBA’s review of available monitoring data of drinking water and groundwater contaminants in Europe shows that these categories of substances represent the largest fraction of substances identified (as of 2017) in drinking water sources. Only 19% are pesticides and their metabolites (62 out of 333 chemicals identified). Moreover, REACH-registered substances *“were the most likely to be found at higher concentrations (above 0.1 µg/L)”*. Therefore, it makes sense to use log Koc cut-off of <4 for M and <3 for vM.

UBA’s report Table C1 *“PMT/vPvM assessment of REACH registered substances (as of May 2017) that have been reported in at least one study as detected in groundwater (GW) or drinking water (DW)”* shows that several very persistent and toxic substances identified in drinking water resources would fall through the net if the highest cut-off value for log Koc was 3, including:

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<sup>3</sup> Arp, H.P. and Hale, S., 2019. REACH: Improvement of guidance and methods for the identification and assessment of PMT/vPvM substances. UBA, November 2019, 131 p.

<https://www.umweltbundesamt.de/publikationen/reach-improvement-of-guidance-methods-for-the>

<sup>4</sup> Neumann, M. and Schliebner, I., 2019. Protecting the sources of our drinking water: The criteria for identifying persistent, mobile and toxic (PMT) substances and very persistent and very mobile (vPvM) substances under EU Regulation REACH (EC) No 1907/2006. UBA, November 2019, 87p.

<https://www.umweltbundesamt.de/publikationen/protecting-the-sources-of-our-drinking-water-the>

- Diclofenac: P/vP, lact. rep. 2 + STOTRE 1., log Koc = 3.8
- TDIP: P/vP, carc. cat 2, log Koc = 3.7
- Benzophenone: P/vP, carc. cat 2 + suspected ED, log Koc = 3.1
- Trichlorobenzene 1,2,4- : P, suspected ED, log Koc = 3.4

### **3. Specific aspects on T and P criteria**

#### 3a. T criteria: environmental Toxicity

*Question 5: Do you agree to consider environmental toxicity when classifying substances as PMT?*

**CHEM Trust supports the inclusion of environmental toxicity in the T criterion including on aquatic and terrestrial organisms.**

CHEM Trust considers that the PMT hazard criteria should aim at protecting both human health and wildlife and ecosystems.

CHEM Trust support the addition of terrestrial organism toxicity to the T criterion currently defined for PBT in REACH Annex XIII, addition. In the context of PMT aiming at protecting natural water resources, not including toxicity on terrestrial organism would be a major oversight as clean drinking water sources are critical for healthy terrestrial ecosystems.

Furthermore, the inclusion of environmental toxicity is consistent with the PBT hazard criteria.

#### 3b. T criteria: human health Toxicity

*Question 6: Do you agree to align the T criteria as suggested above between the PBT and PMT hazard classes?*

**CHEM Trust supports the alignment of the T criteria between PMT and PBT hazard classes and the inclusion of a new criterion for ED category 1.**

**However, CHEM Trust strongly advocates for a more protective approach and recommends to also include Carcinogens category 2, Mutagens category 2 and ED category 2 as well as neurotoxic and immunotoxic compounds.**

#### 3c. P criteria: which compartments to consider

*Question 7: Do you agree to align the P criteria as suggested above between the PBT/vPvB and PMT/vPvM hazard classes?*

**CHEM Trust supports the definition of the P criteria based on all compartments: marine, estuarine, and fresh waters; marine, estuarine, and freshwater sediments; soil.**

All compartments listed above are relevant when considering substances accumulating in the water environment and contaminating drinking water resources for humans and wildlife.

In addition, as it has been pointed out during the discussion on 30 September 2021, marine and estuarine waters are still relevant when considering the protection of drinking water sources. Desalination plants are used to convert sea water into drinking water in several countries in Europe and worldwide.

#### **4. Possibility of categorisation: use of screening criteria**

*Question 8: Do you agree with the conclusion that establishing CLP hazard categories based on PMT/vPvM REACH Annex XIII P screening criteria is not sound as this would lead to over-classification?*

**CHEM Trust supports the establishment of CLP hazard categories for PMT and vPvM hazard classes, in particular the inclusion of suspected categories (category 2)<sup>5</sup>.**

**A category 2 is supported for the following reasons:**

- Including a category 2 would allow to serve the CLP goals better by facilitating hazard identification of harmful PMT/vPvM properties and enabling more transparency and efficient communication in the supply chain.
- It would make the proposal coherent to the current CMR classification with the categories for ‘known and resumed’ CMRs and ‘suspected CMRs’.
- It would enable a better use of the available scientific data which often present a complex picture, may have gaps and lead to inconclusive assessments (also true for current PBT identification, see <https://echa.europa.eu/pbt>).
- It would create an incentive for companies to generate more data in order to prove that a substance suspected to be a PMT/vPvM is not.

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<sup>5</sup> Ninja Reineke, March 2021. How to achieve better protection of the environment and human health from PMT/vPvM substances. Presentation at the 3rd PMT Workshop: “Getting Control of PMT and vPvM substances under REACH”. <https://chemtrust.org/wp-content/uploads/CHEM-Trust-UBA-conference-PMT-March-2021.pdf>

- It would serve the purpose of downstream legislations to address suspected PMT/vPvM.
- It would promote innovation aiming at chemical substitution in order to reduce the accumulation of persistent and potentially harmful substances in the water cycle and natural water resources.
- It would help preventing regrettable substitution of PMT/vPvM chemicals with other potential PMT/vPvM chemicals.

### **Proposal for PMT category 2:**

In CHEM Trust view, the criteria for placing substances in the PMT category 2 merit further discussion. As a starting point we propose a weight of evidence determination which could include a combination of positive results from the screening criteria with additional supporting information for (v)P, (v)M and T properties based on other available evidence. A strong emphasis should be placed on monitoring data, in particular findings in groundwater.

### **5. Alternative approach to animal testing for environmental endpoints**

*Question 9: Do you agree on the introduction of statements supporting the use of test results obtained via alternative approach to animal testing for toxicity and bioaccumulation?*

**CHEM Trust supports the introduction of statements supporting the use of tests results obtained via alternative approach to animal testing for toxicity, as well as a statement supporting the use of read across and grouping in a precautionary manner: always considering the default toxicity equivalent to the most toxic substance in a group until proven otherwise.**

### **8. Hazard communication**

**CHEM Trust recommends that the hazard statements should reflect the specificity of these new hazard classes. Which includes persistence, mobility in the aquatic/water environment, irreversibility, threat to the quality of drinking water, threat to natural water resources. e.g.:**

- Persistent drinking water sources contaminant
- Accumulate in water environment including drinking water sources

It is expected that on the toxicity aspect it will overlap with other existing hazard categories. The relevant hazard statements from the toxic hazard categories should be applied.