EEB and HEAL Comments on the draft PMT/vPvM criteria for CLP

Ad-hoc CARACAL meeting on PMT/vPvM and PBT/vPvB criteria - 30 September 2021

CARACAL document: Ad_hoc_CA_03_2021_Discussion on the draft hazard classes for PMT vPvM in CLP (1)

Introduction

The EEB and HEAL welcome the European Commission's initiative to introduce new hazard classes in the CLP regulation for persistent and mobile substances. The new hazard classes contribute towards achieving the Chemicals Strategy for Sustainability's (CSS) objectives to increase the protection of humans and the environment by phasing out the most harmful chemicals from consumer products and to stimulate innovation towards chemicals that are safe and sustainable by design from start to end of life. Persistent and mobile substances are of high societal and environmental concern, leading to irreversible pollution of drinking water resources now and for future generations. The impact assessment should give due consideration to the societal and environmental benefits of introducing the new hazard classes for PMT and vPvM, including having access to clean drinking water and achieving a toxic free environment. Very persistent chemicals will never disappear.

We welcome the opportunity to provide comments on the draft CLP criteria following the discussion at the Ad-hoc meeting of CARACAL on CLP of 30 September 2021. Our main demands to strengthen the draft Commission proposal on PMT/vPvM criteria are:

1. Our main concern with the proposed draft criteria refers to the Commission proposal to lower the cut-off value for the log Koc criterion. The original proposal in the UBA report is motivated by sound evidence and monitoring data. Therefore, we ask the Commission to **maintain the cut-off value for log Koc < 4 for mobile substances and log Koc < 3 for very mobile substances** respectively. These cut-off values are needed to capture substances with log Koc > 3 that are already detected in drinking water resources.
2. **Introduction of hazard category 2 for suspected PMT and vPvM substances** is an absolute requirement to capture suspected PMT/vPvM substances for which the evidence is not considered sufficient for classification as category 1, in coherence and consistency with the existing classification categories for CMR substances in CLP.

Further justification is provided below in the responses to specific questions in the CARACAL document.

Comments to CARACAL document:

Ad_hoc_CA_03_2021_Discussion on the draft hazard classes for PMT vPvM in CLP (1)

Criteria for PMT/vPvM identification

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

The EEB and HEAL support two hazard classes for PMT and vPvM in analogy with the categories for PBT and vPvB substances respectively. It is important to have a separate hazard class for very persistent and very mobile substances to address the additional concerns. The combination of high persistence and high mobility can lead to widespread and irreversible contamination of the environment across the globe and pose a threat to future generations via the contamination of drinking waters. It should be noted that complete removal of persistent and mobile substances is not economically nor technically feasible. Very persistent chemicals will never disappear.

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?

The EEB supports the proposal to use the combination of log Koc and Persistency to identify mobile and persistent substances. Criteria based on intrinsic hazard properties (like P and log Koc) are suitable for the hazard based approach of CLP and GHS, in analogy with PBT and vPvB criteria and suitable to be introduced at UN level. Log Koc data are widely available, tests are easy to perform and inexpensive.

We would not agree to the introduction of leaching models or experimental leaching tests (like the OECD 312 test guideline). Leaching models are more suitable for site specific and regional exposure assessment and as such these are more suitable for risk assessments, but, in our view, they have no relevance for the hazard-based approach of CLP and GHS. Furthermore, leaching based models may be relevant if looking at direct application to soil, such as pesticides application to soil. However, an important route of entry of persistent and mobile chemicals into the environment is via wastewater, running through the wastewater treatment plant into surface water, followed by wide distribution in the environment, including into groundwater.

Further discussion will be needed regarding the assessment of substances that are ionisable in the environmental relevant pH range, as the ionised form will be more mobile than their neutral form. The use of the minimum experimentally determined log Koc is recommended.

The classification should also take into account the PMT/vPvM properties of relevant constituents of a substance and relevant transformation and/or degradation products.

Use of PMT/vPvM criteria

Question 3: Do you agree that using the definitive PBT/vPvB criteria of Annex XIII to REACH is sound to identify substances as PBT/vPvB under CLP?

We provided an answer to this question in our comments on draft criteria for PBT/vPvB substances. The question seems to be misplaced in this document.

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

No, the EEB and HEAL strongly disagree with the proposal by the Commission to lower the cut-off criteria for log Koc. We propose to maintain the cut-off values proposed in the UBA report: log Koc of 4 for Mobile substances and log Koc of 3 for very Mobile substances[1].

In the original UBA proposal, log Koc of 3 for vM was aligned with the log Koc of 3 selected for the Groundwater Watch list (EC, 2016), accounting for leaching through soil e.g. after direct application of a pesticide on the field. The proposed cut-off value of log Koc of 4 was explicitly selected to protect bank filtration in the production of drinking water. Persistent and mobile chemicals are transported into the environment via private household and industrial wastewater, through the WWTP into surface waters and from there directly into bank filtration. This is a much faster way into the drinking water plant.

The original proposal in the UBA report is motivated by sound evidence and underpinned by monitoring data[2]. Lowering the cut-off value will not capture relevant mobile substances that are already detected in groundwater and drinking water as demonstrated below. The UBA report provides clear evidence of substances with log Koc > 3 that are detected in drinking water sources. 12% of REACH the registered substances that are already detected in groundwater and/or drinking water in monitoring studies have log Koc between 3 and 4, confirming their mobility in the environment, examples include benzophenone, propargite and TCEP. In addition, the SIN list (ChemSec) reveals that relevant substances with log Koc between 3 and 4 are detected in groundwater, including TCPP, the second most often detected organophosphate in groundwater. These substances will not be captured by the lower cut-off values of log Koc 2 and 3.

Several estimates have been made of the number of chemicals that will be identified as PMT or vPvB, using the two proposals for log Koc cut-off. DTU investigated the number of substances that would be excluded from PMT/vPvM identification by lowering log Koc to 2 and 3 compared to the originally

[1] UBA texte 127/2019; 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 1907/20. Michael Neumann, Ivo Schliebner. ISSN 1862-4804

[2] UBA Texte | 126/2019; REACH: Improvement of guidance and methods for the identification and assessment of PMT/vPvM substances. Hans Peter H. Arp, Sarah E. Hale. ISSN 1862-4804

used log Koc 3 and 4 in the DTU QSAR database. The QSAR based screening by DTU revealed a decrease of identified PMT/vPvM from 2% to 0.9% among the 2,037 REACH registered mono-constituent substances > 10 tpa in the database[3]. ECHA provided a "very rough estimation" of the effect of lowering the M/vM threshold from log Koc 3 and 4 to log Koc 2 and 3 and concluded that **lowering the log Koc criterion would decrease the number of identified substances by around 25 %.** Overall, it can be estimated that the set of higher cut-off values (log Koc 3 and 4) will identify around 2% of the chemicals registered under REACH if data are available. Lowering the log Koc criteria to 2 and 3 will reduce the number of chemicals identified as PMT/vPvM to 0.9 - 1.7% of chemicals registered under REACH, and will not capture persistent, mobile and toxic chemicals that contaminate drinking water sources already today.

In conclusion: **the EEB and HEAL propose to include in the impact assessment one scenario with the well-motivated cut-off values proposed in the UBA report**. Persistent chemicals have time to move, they do not degrade or disappear, and consequently low mobility is enough to reach ground water as demonstrated by existing monitoring evidence and justifies the higher cut-off values for log Koc. Lowering the cut-off value to 3 or 2 or even lower, does not allow identification of all substances already detected in drinking water and drinking water sources. The Commission should find the right balance to prevent PMTs and vPvMs reaching the environment, rather than reacting once they pose a threat to health and the environment. Once entered into the environment, the contamination will be irreversible. In the end, it is a policy decision where to put the bar. The question to the Commission and member state authorities is: **is it safe to bring toxic chemicals with log Koc > 3, into the environment, knowing that these chemicals will contaminate our drinking water?**

Specific aspects on T and P criteria

a) T criteria: environmental toxicity

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

We strongly support the consideration of environmental toxicity when classifying substances as PMT, in analogy with the PBT assessment. REACH aims at the protection of both human health as well as the environment. The combination of persistence and mobility introduces an additional concern for the environment due the potential wide distribution across the globe and the long-lasting and irreversible exposure. **The EEB and HEAL welcome the proposed extension of the T criteria in case the substance meets the criteria for identification as an endocrine disrupting chemical for human health or the environment, as well as an extension to allow the use of information on chronic toxicity for terrestrial organisms**.

b) T criteria: human health Toxicity

[3] *How many potential vPvM/PMT substances have been registered under REACH? - vPvM/PMT-screening by using the Danish (Q)SAR database.* Rikke Holmberg, Eva Bay Wedebye, Nikolai Georgiev Nikolov, Henrik Tyle. Available at: https://orbit.dtu.dk/en/publications/how-many-potential-vpvmpmt-substances-have-been-registered-under-

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

The EEB agrees to align the T criteria with the T criteria for PBT substances and we support the extensions proposed for the T criteria for PBT/vPvB substances, including the extension that the substance fulfils T if it meets the criteria for classification as endocrine disruptor for human health or the environment, as well as in the case of evidence of neurotoxicity and immunotoxicity.

c) 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?

We support keeping the P/vP assessment consistent with the PBT/vPvB assessment. Persistency data from all environmental compartments can be used for the identification of persistent or very persistent chemicals, as is currently the case for the PBT and vPvB assessment. These compartments are relevant for the goal of environmental protection as well as protection of drinking water sources, for example in the case of bank filtration. We do note that the information needed to assign P (simulation test), is not required for substances registered at < 100 tpa under REACH. Therefore, we urge that provisions are included that all available, relevant information can be used as currently stipulated in REACH Annex XIII, including use of monitoring data, QSARs, grouping and read-across approaches, etc.

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?

The EEB and HEAL strongly recommend the introduction of a hazard category 2 to identify the substances for which the available evidence does not allow classification as Category 1 PMT or vPvM. For many substances the database is not complete or is inconclusive to assign P, but the available evidence on PMT cannot be ignored either. Therefore, we need a category 2, to capture the substances with evidence of persistence, mobility and toxicity that is not enough to classify as category 1.

The REACH Annex XIII screening criteria are a good starting point for identification of suspected P, vP and T substances. The screening assessment of Annex XIII contains many elements that are suitable for the identification of suspected P/vP and T properties, whereas other elements may need further discussion (such as use of ready biodegradability tests). **Log Koc data are required for all substances registered > 10 tpa under REACH and can be supplemented by information on Log Kow or QSARs for lower tonnage chemicals.**

ECHA estimated that 33% of the substances registered under REACH may fulfil the screening P/vP criteria of Annex XIII and RIVM estimated that 80% of these substances might be screened as M or vM. The estimate that 25% of substances could possibly be identified as suspected PMT/vPvMs can never be an argument for not establishing a category 2. The question to the Commission is whether it is safe to allow toxic chemicals with evidence of high persistence in combination with high mobility

into the environment, knowing that they will ultimately contaminate drinking water sources irreversibly.

Suspected PMTs/vPvMs should be identified to promote the safe use of chemicals and to increase transparency for workers and consumers. The impact assessment should give due consideration to the added benefit for society and the environment of introducing a category 2 for suspected PMTs and vPvMs, including improved protection of human health and the environment, contribution to achieve a non-toxic environment, increased transparency for downstream users facilitating innovation and substitution by safer alternatives and increasing transparency for citizens about the presence of suspected dangerous chemicals in consumer products.

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?

As pointed out previously, the EEB and HEAL strongly recommend that a provision on the use of wider evidence for identification of PMT/vPvM be copied into the CLP regulation, in analogy and consistency with the current REACH Annex XIII annex. Other evidence can be used provided that it is derived by internationally recognised validated methods for the identification of the T property. Furthermore, the use of grouping approaches and read-across to similar substances can help to build the weight of evidence for classification as a PMT or a vPvM substance.

The use of alternative approaches to animal testing is not a specific issue for PMT substances, but a general issue relevant as well for other hazard classes. Therefore, we believe that this could be dealt with in a consistent way for all hazard classes concerned in the general text of the CLP regulation.

Way to harmonise the implementation of the criteria

Question 10: Should the section providing the criteria for PBT and vPvB in the CLP also provide for a harmonised approach or should it be left to the CLP guidance document?

We believe that a guidance document is more suitable to address clarifications on the implementation of the PBT and vPvB criteria rather than the regulatory text of CLP.

Classification of mixtures:

Question 11: Do you agree to base the mixture classification on the presence of classified substances in the mixture? Do you consider it sound to avoid specifying a cut off value?

We support the proposal to classify a mixture if at least one substance contained in the mixture can be classified as PMT or vPvM. For PMT / vPvM substances no safe concentrations can be defined. A threshold value could lead to unacceptable emissions and would contradict the principle that these substances need a qualitative risk assessment and an exposure reduction as far as possible (in line with REACH Annex I .4). Therefore, no threshold should apply for the classification of mixtures.

Furthermore, data on whole mixtures cannot be used for the purpose of classification. Instead, toxicity should be assessed based on the substances contained in the mixture, and not be based on the toxicity of the mixture as whole.

Question 12: When it comes to substances with more than one constituent, do you think the same reasoning as for mixtures should apply? Do you think that for T, data on the MOCS itself can be used?

The same reasoning should apply for mixtures and MOCS and hence, it makes no sense to use for the toxicity assessment, data that are based on the MOCS itself. We suggest following the ongoing discussion at CARACAL on this topic.

Hazard communication

We recommend that the hazard communication covers the threats specific for the new hazard classes, including the persistence, long range transport, long lasting effects, and contamination of groundwater and drinking water sources.