

CropLife Europe input on PMT/vPvM criteria in response to CARACAL Meeting (Ad-hoc CA/03/2021)

Priorities

- CropLife Europe wishes to caution that the rushed adoption of the PMT criteria may result in a regulation not fit for purpose. As the newly introduced hazard classes will be referred to across the regulatory landscape, a clear understanding of the practical consequences affecting all types of chemicals in scope of CLP Regulation is necessary prior to a legislation proposal being introduced.
- **Leachability** defined as percentage of a chemical that can reach drinking water sources represents the best parameter to define the mobility criterion (M). CropLife Europe proposes categorisation based on the M criterion:
 - o Confirmed PMT (Category 1) based on leachability
 - o Suspected PMT (Category 2) based on K_{oc}**P and T criteria would remain unchanged (i.e., confirmed only).**
- **CLE does not support a separate hazard class for vPvM nor the expansion of the T criterion to terrestrial toxicity due to lack of sufficient scientific evidence.**

Scope of CLP Regulation and Interlinks within the EU Regulatory Landscape

As stated in the legal text, the objective of CLP Regulation is to “*determine which properties of substances and mixtures should lead to a classification as hazardous, in order for the hazards of substances and mixtures to be properly identified and communicated*” [1]. Therefore, CLP is mainly a tool for chemicals management according to the provisions outlined in different pieces of legislation, e.g., SVHC designation under REACH, non-authorisation under Plant Protection Products Regulation (PPPR).

With REACH in focus, **the impact of classification and the interlinks between CLP and other regulations (PPPR, Biocidal Products Regulation, etc.) is frequently not given sufficient consideration.** This has been exemplified in the PMT background document (Ad hoc CA/03/2021) which exclusively addresses REACH chemicals. In addition, the European Commission (COM) specifically noted at the meeting that impact assessment conducted for the CLP revision would “not consider sectorial legislation” and would be focused “solely on CLP” – again presumably referring to chemicals *managed* under REACH (note: approved pesticide active ingredients are considered to be *registered* under REACH). As CLP Regulation as a general principle applies to all substances supplied in the EU, **CLE wishes to emphasize that newly introduced hazard classes will be referred to across all relevant legislation and that any impact assessment needs to take into account all chemicals in scope of CLP.**

Newly proposed hazard classes for identifying PMT and vPvM substances

As outlined by the Commission, the goal of introducing new hazard classes related to PMT and vPvM properties is “*to protect natural resources that could be used for drinking purposes from chemical pollution*”. The rationale is that a combination of persistent (P), mobile (M) and toxic (T) properties poses a hazard.

COM initial proposal is to establish two hazard classes: one for PMT and one for vPvM. Whilst the proposal presumably relies on perceived equivalence with existing PBT criteria, the **analogy between vPvB and vPvM is questionable.** The underlying assumption for vPvB substances is that they could reach irreversible internal concentrations much higher than in the environment and that their low degradation potential would further enhance bioaccumulation, leading to potential adverse effects irrespectively of lack of toxicity.

Whilst it is evident that a PMT substance might pose a hazard, the concern for non-toxic very persistent and very mobile (vPvM) substances seems to be unfounded and not sufficiently supported by scientific evidence. A nontoxic mobile substance would not pose a hazard to a drinking water source (nor any organisms that live in it), irrespectively of its potential persistency. Therefore, **CLE does not support a separate hazard class for vPvM substances to be established.**

The Mobility Criterion: Necessity for a robust and accurate assessment

As suggested by COM in the PMT background document (Ad hoc CA/03/2021), the combination of P (persistence) and M (mobility) properties poses a concern due to increased chances for such substances “to pass natural barriers like riverbanks and artificial barriers in water treatment facilities”. In combination with T (toxicity), such a substance poses a hazard to a drinking water resource.

It is important to note that whilst the assessments of persistency and toxicity are well established in the EU, criteria for mobility in the context of PMT assessment have never been agreed nor implemented in any regulatory framework. With this in mind, **CLE wishes to caution that the rushed adoption of the criteria and the inadequate timeframe for further development of better targeted approaches for the chemicals that really matter may pose both a missed opportunity and result in a regulation not fit for purpose.**

PMT Assessment: Tiered approach for mobility

The organic carbon-water partition coefficient (K_{oc}) was proposed as the only criterion to characterize mobility within PMT. However, it solely indicates the tendency of a chemical to adsorb to particles – with some limitations. Even the OECD test guideline for determining the K_{oc} indicates that “*numerous phenomena and mechanisms involved in the process of adsorption of a chemical by soil cannot be completely defined by a simplified laboratory model*” [2].

As described in ECETOC Technical Report [3], **K_{oc} is a poor metric for mobility** and does not reflect the actual potential of a substance to reach drinking water sources. For example, a chemical with a short half-life in soil (but considered P in water based on current criteria within REACH PBT assessment) may be completely degraded before reaching a drinking water source. Without going into further details, it is important to note here that current criteria used for P assessment in water within the PBT framework may not be suitable to be used in conjunction with K_{oc} . In addition, the use of K_{oc} alone to define mobility has been documented to result in high number of false positives and false negatives [4].

CLE believes that leachability defined as percentage of a chemical that can reach drinking water sources represents the best parameter to define the mobility criterion (M). In order to support the leachability criterion and provide an assessment framework, a simple *in silico* tool based on a well-established leaching modelling approach [5, 6] to determine leachability as function of K_{oc} and soil DT50 was developed and results were made available.¹ We would like to clarify that **the combination of K_{oc} and soil DT50 is meant to characterise solely the M criterion**, whilst the P criterion would still be assessed separately.²

The COM background document criticises the *in silico* approach for being context-specific for EU environmental conditions and therefore unsuitable for GHS, and for being more suitable for risk assessment and hence unsuitable for CLP. In response we would like to state the following:

- Current PBT (and presumably future PMT) **criteria are based on EU thresholds not in line with other regulatory frameworks.** This on its own may be enough to jeopardise the GHS adoption if seen as an attempt to impose European framework on the rest of the world.
- **P criterion is always context-specific.** Half-lives are calculated based on studies conducted under specific reference conditions and using specific matrices, e.g., the reference temperature of 12 °C “*which is regarded as a reasonable alleged average temperature for the European Union*” [7]. Following the same logic as outlined in the criticism of the proposed leachability approach, European P assessment would not be suitable at UN level, where different regions have very different conditions.
- **It is important to distinguish between the criterion (leachability) and a tool (*in silico* approach).** We argue that leachability is a more accurate mobility parameter than the K_{oc} value alone. Whilst the criterion would be introduced in the legal text, the assessment procedure would be described in the guidance document. This would provide an opportunity for further development and refinement of the tool, as well as potential expansion and adjustment to other regions.

¹ Results of leachability calculations performed with the *in silico* tool are available at [CLE website](#).

² This may not be evident in the PMT background document (Ad hoc CA/03/2021).

- **The tool was developed specifically for hazard assessment.** Leachability calculation is not dependent on exposure and is based solely on substance properties.

In addition to the leachability interpretation provided in the PMT background document, COM noted at the CARACAL meeting that the thresholds for the mobility criterion based on leachability would need to be supported by further evidence. In a first evaluation the leachability approach was compared with groundwater monitoring data from France (ADES data base of BRGM) including 236 PPP substances and more than 22,000,000 individual samples. It was found that for all substances for which leachability below 1% was predicted only a negligible fraction of samples showed concentrations greater than the legal threshold. Leachability is therefore a robust approach consistent with observed monitoring data for groundwater and the **proposed threshold of 1% would sufficiently discriminate mobile from non-mobile substances** with regard to the stated protection goal.

CLE would like to note that this work is ongoing and will be made available for the public consultation on CLP revision. The current timeframe was not sufficient to provide documented results at this point.

Whilst we maintain that leachability would be the most appropriate mobility criterion, we do acknowledge that the K_{oc} alone can provide an initial indication of potential for mobility, bearing in mind the already noted caveats on correlation with physical processes in soil and the constrained experimental applicability domain within chemical space. Taking into account that existing P and T criteria are well established and that the M criterion is being introduced for the first time, **CLE would like to propose categorisation for the PMT hazard class based on the M criterion alone:**

- **Confirmed PMT (Category 1):** Confirmed P and T based on current thresholds, confirmed M based on the leachability criterion;
- **Suspected PMT (Category 2):** Confirmed P and T based on current thresholds, suspected M based on the proposed K_{oc} value.

This kind of a tiered approach would ensure that any potentially hazardous substances are flagged, but that only substances posing a real danger to drinking water sources are considered as confirmed PMTs and managed accordingly in corresponding sectorial legislation.

The toxicity criterion

The current proposal for PMT classification considers environmental toxicity in line with the current T criterion within the PBT framework, but also notes that terrestrial toxicity would be added. However, *“other evidence for chronic toxicity for terrestrial organisms”* is not a sufficient classification criterion and would require precisely defined thresholds. Initiatives to establish terrestrial toxicity criteria for classification at EU and UN level have repeatedly failed in the past, primarily due to lack of adequate data. GLP terrestrial toxicity studies are scarce in comparison with aquatic toxicity studies, which can be illustrated by the fact that well over 50% of terrestrial data in REACH originate from publicly available literature and are yet to be assessed for reliability [7]. These points were raised at the PROSOIL Expert Workshop (UBA, June 2021), where it was noted that better understanding and transparency of the reliability and comparability of data is still needed in order to derive thresholds and toxicity ranges in the context of CLP and PBT. **CLE consider that it would be premature to incorporate terrestrial toxicity into the T criterion prior to further discussion at both EU and UN level and disagree with incorporating terrestrial toxicity into the T criterion.**

Data availability, harmonisation, and impact across the regulatory landscape

Any assessment on potential number of substances to be classified as PMT needs to rely on conclusive data. The PMT background document (Ad hoc CA/03/2021) notes that *“up to 1.7% of the REACH registered substances may potentially be captured as PMTs/vPvM”* based on the UBA criteria, and that the currently proposed criteria would further decrease this number by around 25%. However, the document also notes that ECHA screened 2,073 mono-constituent organic substances registered under REACH, and that about 231 substances of the registered substances may be identified as PMT/vPvM *provided that the data was available*. However, the data are not available for most substances. It is very important to note that, due to the way REACH data requirements were set up, most registrants had an option to waive adsorption/desorption studies for potentially mobile substances. It is highly likely that the number of PMT substances under the currently proposed criteria will be much higher than noted in the background document.

On the other hand, plant protection products represent the most data-rich group of chemicals and a good case study on the impact of the newly proposed criteria. CropLife Europe performed an initial screening exercise on pesticide active substances registered in the EU and submitted the results to COM and ECHA in September.

The results indicated that **a minimum of 76% of pesticide active substances would be considered M/vM under the current K_{oc}-based proposal (M for logK_{oc}<3, vM for logK_{oc}<2).**

Here it is very important to note that whilst the P and T criteria are identical in REACH Annex XIII and PPPR Annex II, the implementation differs (reference temperature, NERs interpretation, metabolites consideration, etc). The initial screening exercise submitted to COM and ECHA in September noted that a minimum of 22% of PPP active ingredients would be considered PMT/vPvM under the currently proposed criteria, but that this number would be much higher if all the criteria were implemented in line with the REACH guidance. The updated assessment notes that **around 70% of PPP active substances registered in the EU would be considered PMT/vPvM under the currently proposed criteria (M for logK_{oc}<3, vM for logK_{oc}<2) if REACH guidance is followed with respect to the P criterion.** If the originally proposed criteria (M for logK_{oc}<4, vM for logK_{oc}<3) are applied, around 80% of the PPP substances would be considered PMT/vPvM. If the M criterion would be based on leachability, around 40% of active substances would likely be considered PMT/vPvM.

Since monitoring data from drinking water resources of different countries show that only a small number of substances at very low frequency is found at concentrations greater than the legal drinking water limits it can be concluded that the **vast majority of PPPs classified as PMT/vPvM substances would be false positives.**

The drastic difference in numbers of impacted substances dependent on criteria implementation illustrates the need for careful consideration when it comes to harmonisation. Regulatory Fitness and Performance programme (REFIT) of the PPP Regulation concluded that the regulation is overall effective and contributes to the protection of both human health and the environment [9]. It is important to note that no concerns were identified with regards to PBT assessment and the current criteria implementation.

Taking into account both the complexity of the topic and the extremely compressed timeframe for the CLP revision, CLE calls for the CLP Regulation to refer solely to the criteria. Details on harmonisation could be discussed during the guidance document update following the criteria adoption.

References:

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