EEB and HEAL comments on the draft PBT/vPvB criteria for CLP

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

Introduction

The EEB and HEAL welcome the European Commission's initiative to introduce new hazard classes in the CLP regulation for PBT/vPvB 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. We welcome the opportunity to provide comments on the thought starter on draft CLP criteria for PBT/vPvB discussed at the Ad-hoc meeting of CARACAL on CLP of 30 September 2021.

The EEB and HEAL support the Commission's proposal to use the provisions of REACH Annex XIII as a starting point to establish hazard classes for PBT and vPvB substances in the CLP regulation. The Commission states in the document to aim at deleting provisions related to PBT/vPvB identification in other legislations, including REACH. We note that further discussion will be needed on how to establish the most protective and effective interlinkage between REACH, CLP and other legislations.

We would like to highlight here our two main proposals to strengthen the draft Commission proposal on PBT/vPvB criteria:

1. **Introduce hazard category 2 for suspected PBT and vPvB substances**. Category 2 is an absolute requirement to capture suspected PBT/vPvB 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.

2. **Include provisions in the CLP regulation that allow the use of all relevant, available information for the purpose of classification** as currently foreseen in REACH Annex XIII for the identification of PBTs and vPvBs, which includes the use of monitoring data, (Q)SARs, grouping, read-across approaches, etc.

Further details motivating these requests and responses to the specific questions raised by the Commission in the CARACAL documents are provided below.

Comments to CARACAL document:

Ad_hoc_CA_02_2021_Thought starter - draft hazard classes for PBT vPvB in CLP

Possibility of categorisation: use of screening criteria

Question 1: Do you agree with the conclusion that establishing CLP hazard categories for suspected PBT/vPvB based on PBT/vPvB REACH Annex XIII screening criteria is not sound?

The EEB and HEAL strongly recommend the implementation of hazard categories for suspected PBT/vPvB substances. The data available in the registration dossiers are not sufficient to allow identification of PBT and vPvB properties for many substances. Such data are not required for lower tonnage chemicals (registered volume < 100 tpa), and also higher tonnage chemicals suffer from incomplete and inconclusive data sets in this respect. The urgency for hazard categories for suspected PBTs/vPvBs is underpinned by the own statements of the Commission in the document: The Commission stipulates in the document that currently "*The REACH Candidate list includes about 108 substances identified as confirmed PBT and/or vPvB";* whereas it is estimated "*that there could be about 400 of all registered substances (23,751 substances) which may be identified as PBT/vPvB if data were available".* Therefore, it is absolutely necessary to establish CLP hazard categories to capture suspected PBTs and suspected vPvBs with evidence of PBT and vPvB properties that is not considered sufficient to classify as category 1, in coherence with the CLP's CMR categorisation.

The second question to be answered is then whether the CLP hazard categories for suspected PBT/vPvB can be based on REACH Annex XIII screening criteria. **The EEB and HEAL believe that the screening criteria set out in REACH Annex XIII are a good starting point to discuss criteria for category 2.** The screening assessment of Annex XIII contains many elements that are suitable for the identification of suspected PBT and vPvB substances, whereas some further discussion may be needed on other elements (for example on use of ready biodegradability tests).

The impact assessment should give due consideration to the added benefit for society and the environment of introducing a category 2 for suspected PBTs and vPvB, 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.

Use of PBT criteria

Question 2: Do you agree that using PBT/vPvB criteria of Annex XIII to REACH A XIII is sound to identify in CLP substances as PBT/vPvB?

The EEB and HEAL support the use of the REACH Annex XIII criteria for the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances. **We do note however that text should be added to allow for the use of other available evidence for the classification of PBT and vPvB substances as is currently provided in REACH Annex XIII.** The text in

REACH Annex XIII allows the use of all relevant information for PBT and vPvB identification, especially in cases where the available information does not allow the direct application of the PBT and vPvB criteria. Information to be considered includes the use of monitoring data, (Q)SAR results, grouping approaches and read-across to similar substances, etc. as currently specified in REACH Annex XIII.

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, neurotoxicity or immunotoxicity.

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

Alternative approach to animal testing for environmental endpoints

Question 3: 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 PBT/vPvB be copied into the CLP regulation, in analogy and consistent 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. Also, the use of grouping approaches and read-across to similar substances can help to build the weight of evidence for classification as a PBT or vPvB substance.

The use of alternative approaches to animal testing is not a specific issue for PBT and vPvB 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 4: Should the section providing the criteria for PBT and vPvB in the CLP be complemented to achieve *a harmonised implementation approach (consequently repealing any implementation approaches in other legislation) or should this aspect be left for 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.

T criteria

Addition of EDs (HH and ENV)

The EEB and HEAL support including an additional criterion for T if the substance meets the criteria for classification as an endocrine disruptor for human health or the environment, as well as an extension to allow the use of information on chronic toxicity for terrestrial organisms, neurotoxicity and immunotoxicity.

Classification of mixtures

Question 5: 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 PBT or vPvB. For PBT / vPvB substances no safe concentration levels 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 6: 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 using toxicity data that are based on the MOCS itself. We suggest following the ongoing discussion at CARACAL on this topic.

Hazard communication

Question 7 – What are the views of the experts regarding the hazard communication strategy proposed for PBT and vPvB? Would the experts consider applying the hazard communication for aquatic chronic toxicity to all PBT, vPvB whether they are chronically toxic to aquatic organisms or not?

The EEB and HEAL do not support the use of the same hazard communication as currently in place for aquatic chronic toxicity. The severity of the hazards posed by PBT and vPvB substances requires specific hazard communication. For example, the signal word Danger is warranted in case of PBT and vPvB substances, rather than the currently used signal word Warning for Chronic aquatic toxicity Cat. 1. Additional Hazard and Precautionary statements are needed as well to reflect the specific concerns of PBT and vPvB substances.