New CLP classification requirements for persistent substances

With this information sheet FoBiG would like to inform you about current developments regarding the classification of substances and mixtures regarding possible persistent (P), bioaccumulative (B) and toxic (T) properties (PBT); very persistent and very bioaccumulative properties (vPvB); persistent, mobile (M) and toxic properties (PMT); as well as very persistent and very mobile properties (vPvM).

With the Commission Delegated Regulation (EU) 2023/707, which entered into force on 20 April 2023, Regulation (EC) No. 1272/2008 (CLP Regulation) has been extended to include new hazard classes. In addition to new hazard classes for substances with endocrine-disrupting properties[1], new hazard classes were defined for substances that are poorly degradable in the environment (PBT / vPvB and PMT / vPvM). The classification procedure follows closely the PBT / vPvB assessment according to REACH Annex XIII but is independent of the registered tonnage under REACH[2]. Consequently, a possible assignment to the following new hazard classes needs to be considered for all substances:

PBT / vPvB		
PBT	EUH440	Accumulates in the environment and living organisms including in humans
vPvB	EUH441	Strongly accumulates in the environment and living organisms including in humans
PMT / vPvM		
PMT	EUH450	Can cause long-lasting and diffuse contamination of water resources
vPvM	EUH451	Can cause very long-lasting and diffuse contamination of water resources

The following **deadlines** apply to labelling:

Substances must be labelled no later than 1 May 2025. Substances placed on the market before 1 May 2025, do not have to be labelled until 1 November 2026.

Mixtures must be labelled no later than 1 May 2026. Mixtures placed on the market before 1 May 2026, do not have to be labelled until 1 May 2028.

At first glance, the deadlines appear sufficiently long, especially considering that the PBT / vPvB assessment as required under REACH has largely been adopted in the update of the CLP regulation, with only few differences introduced. However, the CLP Regulation also necessitates the classification of substances of low tonnage for which important data on P, B, T and M properties may be missing. Furthermore, the CLP Regulation requires a laborious weight of evidence (WoE) approach integrating diverse data types in addition to actual '*assessment*' information (as far as available) to derive a conclusion on each hazard class. Based on the REACH guidance documents currently being updated (Guidance on IR & CSA R.11 and R.7b/c), we expect a stronger focus on bioaccumulation in air breathing animals (mammals and birds) for classification as well, increasing the workload significantly. Furthermore, the mobility assessment can be demanding for some substances. The corresponding ECHA CLP Guidance is only expected by mid-2024. Since a high evaluation effort may be required for some substances (including potential additional testing), it is not meaningful to wait until the publication of the CLP Guidance.

Considering that company-internal preparatory work is necessary to identify substances with high priority and high evaluation effort, we recommend to screen and prioritize the substance portfolio at an early stage.

FoBiG has developed strategies internally to address these endpoints. We are happy to support you with all questions and tasks in this context.

Please do not hesitate to **contact** us: markus.schwarz@fobig.de

[1] see FoBiG information sheet: New classification requirements for possible endocrine disrupting effects

[2] Note that under REACH, the assessment for PBT / vPvB properties only needs to be performed for substances requiring a chemical safety assessment, i.e. at a tonnage level ≥10 t/a.