



Regulation of Persistent and Mobile substances at the European level: Regulatory developments and CLP Guidance development

07 May 2024, Seville

SETAC Europe 34th Meeting

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Outline

- Introduction and regulatory context;
- Hazard classification criteria for PMT/vPvM substances
- CLH process and CLP Guidance development;
- Mobility (M/vM) assessment under CLP: Use of available information, and
- Status and next steps of the Guidance development.

Regulatory context

- The Classification, Labelling and Packaging (CLP) Regulation (1272/2008) ensures a high level of protection for human health and the environment.
- ECHA supports the implementation of the CLP regulation by providing technical, scientific and administrative tasks support.
- Commission Delegated Regulation 2023/707 amending CLP Regulation (EC) No 1272/2008 published on 31/03/2023
- New hazard classes:
 - ✓ ED HH in Category 1 and Category 2 (Endocrine disruption for human health);
 - ✓ ED ENV in Category 1 and Category 2 (Endocrine disruption for the environment);
 - ✓ PBT (persistent, bioaccumulative, toxic), vPvB (very persistent, very bioaccumulative), and
 - ✓ PMT (persistent, mobile, toxic), vPvM (very persistent, very mobile).

Protection goal for PMT/vPvM substances

- ! High persistence + High mobility (low adsorption potential);
- ! Substances may enter the water cycle (including drinking water, reach long distances) ;
- ! Partially removed by wastewater treatment processes or water purification processes.



- ☞ Concentration of those PMT and vPvM substances in the environment (water resources) can increase over time.
- ☞ Exposure of both animals and humans via the environment.

Mobility

REACH in Annex II section 12.4 defines mobility in soil as: *"the potential of the substance or the components of a mixture, if released to the environment, to move under natural forces to the groundwater or to a distance from the site of release"*.

Commission Delegated Regulation 2023/707: *"The Koc value [...] reflects the ability of a substance to be adsorbed on the organic fraction of solid environmental compartments such as soil, sludge and sediment, and is therefore inversely related to the substances' potential of entering into ground water.*

- Mobility is a "novel" hazard assessment criterion;
- LogKoc is a standard information requirement under REACH (Annex VIII) and BPR (Annex II);
- Limited experience on assessing Mobility under REACH and CLP (Hazard assessment), and
- Leaching studies under PPP and BPR (Risk assessment).

Hazard classification criteria for PMT/vPvM substances

| Persistence | P criteria | vP criteria |
|----------------------------|------------------------|------------------------|
| Medium | Half-day (days) | Half-day (days) |
| Water (marine) | >60 | >60 |
| Water (fresh /estuarine) | >40 | >60 |
| Sediment (marine) | >80 | >180 |
| Sediment (fresh/estuarine) | >120 | >180 |
| Soil | >120 | >180 |

Same as in REACH, Annex XIII

| Mobility | M criteria | vM criteria |
|-----------------------------------|-------------------|--------------------|
| LogKoc (soil, sludge or sediment) | <3 | <2 |

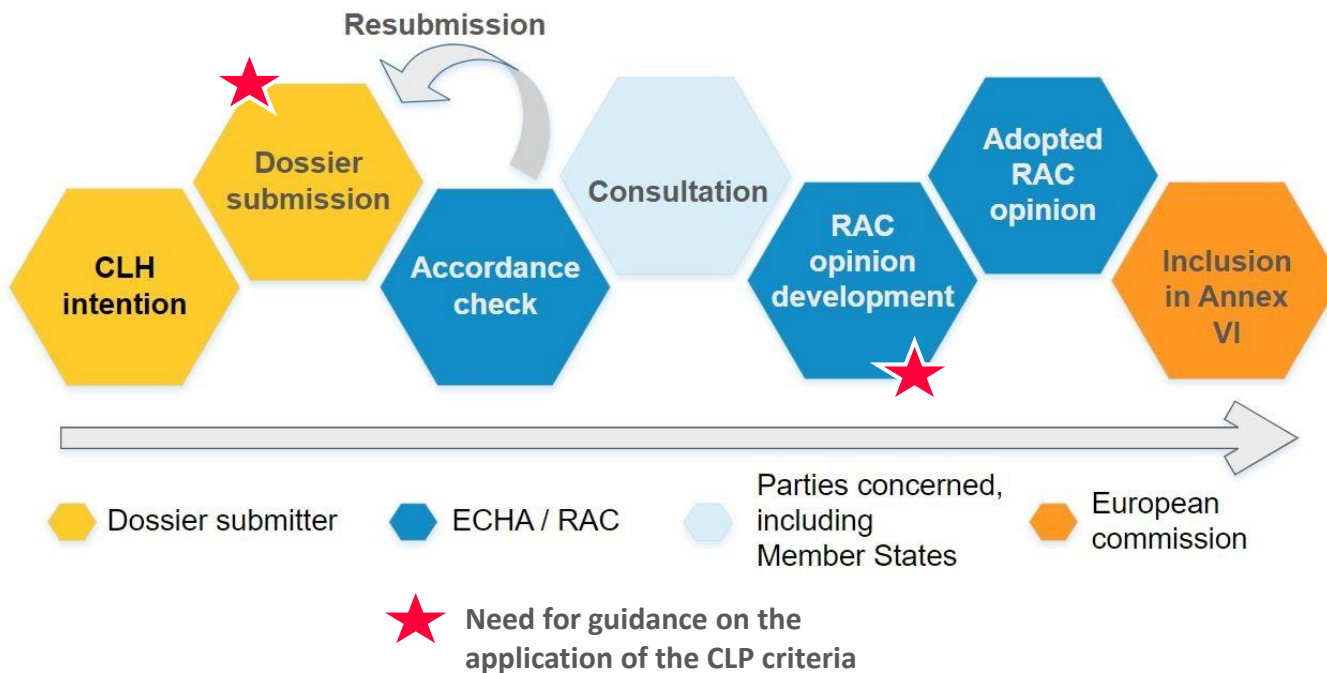
! NEW !

| Toxicity | T criteria | |
|--------------------|--|----------------------|
| | Exposure duration | Value (mg/L) |
| Ecotoxicity | Chronic NOEC or EC ₁₀ | <0.01 |
| | Endpoint | Category |
| Mammalian toxicity | Carcinogenic | Category 1A or 1B |
| | Germ cell mutagenic | Category 1A or 1B |
| | Toxic for reproduction | Category 1A, 1B or 2 |
| | Specific target organ toxicity after repeated exposure | Category 1 or 2 |
| | Endocrine disruption | Category 1 |



CLH process

- New Hazard classes in force as of **20 April 2023**
- Member States can make proposals for harmonised classification and labelling (CLH)



CLP Guidance development on the Application of the CLP Criteria

→ Current guidance includes:

- Physical hazards;
- Health hazards, and
- Environmental hazards-Aquatic toxicity and hazard to ozone layer.



→ Guidance on the application of the **NEW** CLP criteria:

- PMT/vPvM;
- PBT/vPvB;
- ED Human Health (Category 1 and Category 2), and
- ED Environment (Category 1 and Category 2).

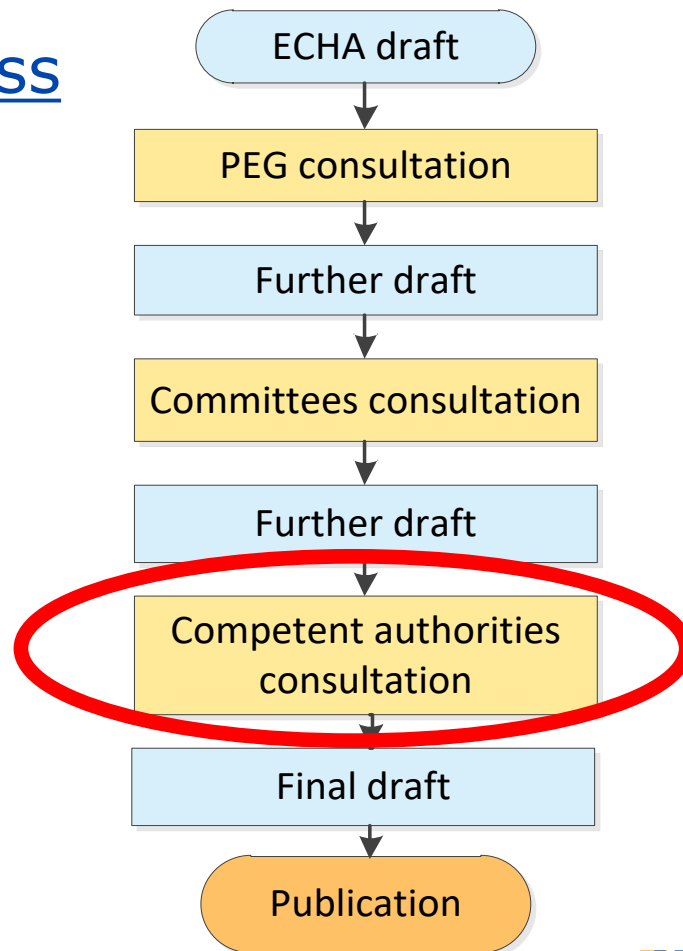


Guidance development process

When ECHA identifies a need for updating existing guidance or for developing new guidance, it will prepare a corresponding draft document.

A consultation procedure will be initiated based on this first draft and that will follow the following steps:

- Consultation of a Partner Expert Group (PEG);
- Consultation of ECHA's Committees, and
- Concluding consultation of the European Commission and the relevant Competent Authorities.



CLP Guidance development on the Application of the NEW CLP Criteria

- CLP criteria for PBT/vPvB and **PMT/vPvM** substances;
- Identification and assessment of hazard information for PBT/vPvB and PMT/vPvM substances:
 - Persistence;
 - Bioaccumulation;
 - **Mobility**, and
 - Toxicity
- Application of the WoE to conclude on PBT/vPvB and **PMT/vPvM** properties and classification and labelling;
- Classification criteria for PBT/vPvB and **PMT/vPvM** mixtures;
- Hazard communication elements for PBT/vPvB and **PMT/vPvM** substances, and
- Examples PBT/vPvB and **PMT/vPvM** substances

Mobility (M/vM) assessment under CLP

The following information shall be considered:

a) Results from adsorption/desorption testing

- OECD TG 106 (Adsorption - Desorption Using a Batch Equilibrium Method);
- Studies on activated sewage sludge (OPPTS 835.1110 and ISO 18749);
- OECD TG 121 (Estimation of the Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC));
- OECD TG 312 (Soil leaching columns), and
- Soil thin and thick layer chromatography (TLC).

Mobility (M/vM) assessment under CLP

b) other information such as information from leaching, modelling or monitoring studies, provided that its suitability and reliability can be reasonably demonstrated.

Also, in applying the WoE determination, the following information, shall be considered:

- i. Organic carbon to water partition coefficient (K_{oc}) estimated by well-developed and reliable (Q)SAR models;
- ii. Other information, provided that its suitability and reliability can be reasonably demonstrated.

Mobility (M/vM) assessment under CLP

- Weight of Evidence (WoE) using expert judgment:
- description of the general principles and steps
 - use of data obtained under relevant conditions;
 - use of data on relevant constituents, additives or impurities of a substance and relevant transformation or degradation products, and
 - treatment of results from multiple studies:
 - Most conservative of the relevant and reliable values;
 - Combination of several reliable study results conducted under the same test type (for example, OECD TG 106), and
 - Study results from different study types cannot be combined.

Status and next steps of the guidance development

- **Next steps (tentative timelines):**
 - **CARACAL consultation (June-August, 2024)**
 - **Publication (Autumn, 2024)**
- **Follow the status of the CLP Guidance development:**



Thank you

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