



# Regulating persistent and mobile substances at a European level: Regulatory developments and CLP Guidance development

23 May 2024, ZeroPM webinar

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# Introductory statements

- ECHA following with great interest scientific developments in relevant EU research Projects
- Active participation in European Partnership for the Assessment of Risks from Chemicals (PARC, <https://www.eu-parc.eu/>)
  - ✓ ECHA's role in PARC is to make sure that the funded scientific research addresses current challenges related to chemical risk assessment and adds value to the EU's regulatory processes
- Observer status at ZeroPM, presentation during February 2023 Gothenburg meeting

# Outline

- Short historical evolution of Legislation for Classification & Labelling
- ECHA's role under CLP
- CLH process
- New hazard classes and regulatory criteria
- Guidance development
- Mixture classification
- Next steps

# Historical evolution of Legislation for classification

- The Dangerous Substances Directive (DSD, 67/548/EEC) on the classification, labelling and packaging of dangerous substances
- The Globally Harmonized System of Classification and Labelling of Chemicals (GHS, first edition 2002)
- The Classification, Labelling and Packaging (CLP) Regulation (EC No 1272/2008) replaced the DSD => ECHA to manage
- Purpose and scope: ensure a high level of protection of human health and the environment, as well as the free movement of substances, mixtures and articles

# Historical evolution of Legislation for classification

- Harmonisation of classification and labelling by introduction of hazard classes, statements, pictograms, etc. for industrial chemicals, pesticides, biocides
  - ✓ Physical (e.g. explosivity, flammability, etc.), human health (e.g. mutagenicity, carcinogenicity, etc.), aquatic hazards and hazardous to the ozone layer
- CLP Annex VI contains the list of harmonised classification and labelling of hazardous substances
- Obligations for manufacturers, producers of articles, importers, suppliers and downstream users

# CLP Annex VI

Table 3

List of harmonised classification and labelling of hazardous substances

| Index No     | ►M18 Chemical name ◀      | EC No     | CAS No     | Classification                    |                          | Labelling                      |                          |                         |
|--------------|---------------------------|-----------|------------|-----------------------------------|--------------------------|--------------------------------|--------------------------|-------------------------|
|              |                           |           |            | Hazard Class and Category Code(s) | Hazard statement Code(s) | Pictogram, Signal Word Code(s) | Hazard statement Code(s) | Suppl. H statement Code |
| 001-001-00-9 | hydrogen                  | 215-605-7 | 1333-74-0  | Flam. Gas 1<br>Press. Gas         | H220                     | GHS02<br>GHS04<br>Dgr          | H220                     |                         |
| 001-002-00-4 | aluminium lithium hydride | 240-877-9 | 16853-85-3 | Water-react. 1<br>Skin Corr. 1A   | H260<br>H314             | GHS02<br>GHS05<br>Dgr          | H260<br>H314             |                         |
| 001-003-00-X | sodium hydride            | 231-587-3 | 7646-69-7  | Water-react. 1                    | H260                     | GHS02<br>Dgr                   | H260                     |                         |
|              |                           |           |            |                                   |                          |                                |                          |                         |

# Historical evolution of Legislation for classification

- Commission Delegated Regulation 2023/707 amending CLP published end of March 2023
- Introduction of new hazard classes
  - ED HH and ENV (Cat 1 and 2); PBT/vPvB; PMT/vPvM
- As of 20 April 2023, harmonised proposals on the new hazard classes can be submitted [first one on EDs already submitted early May 2024]
- ECHA supports the implementation of the CLP Regulation by providing technical, scientific and administrative support

# What is ECHA Secretariat's mandate under CLP

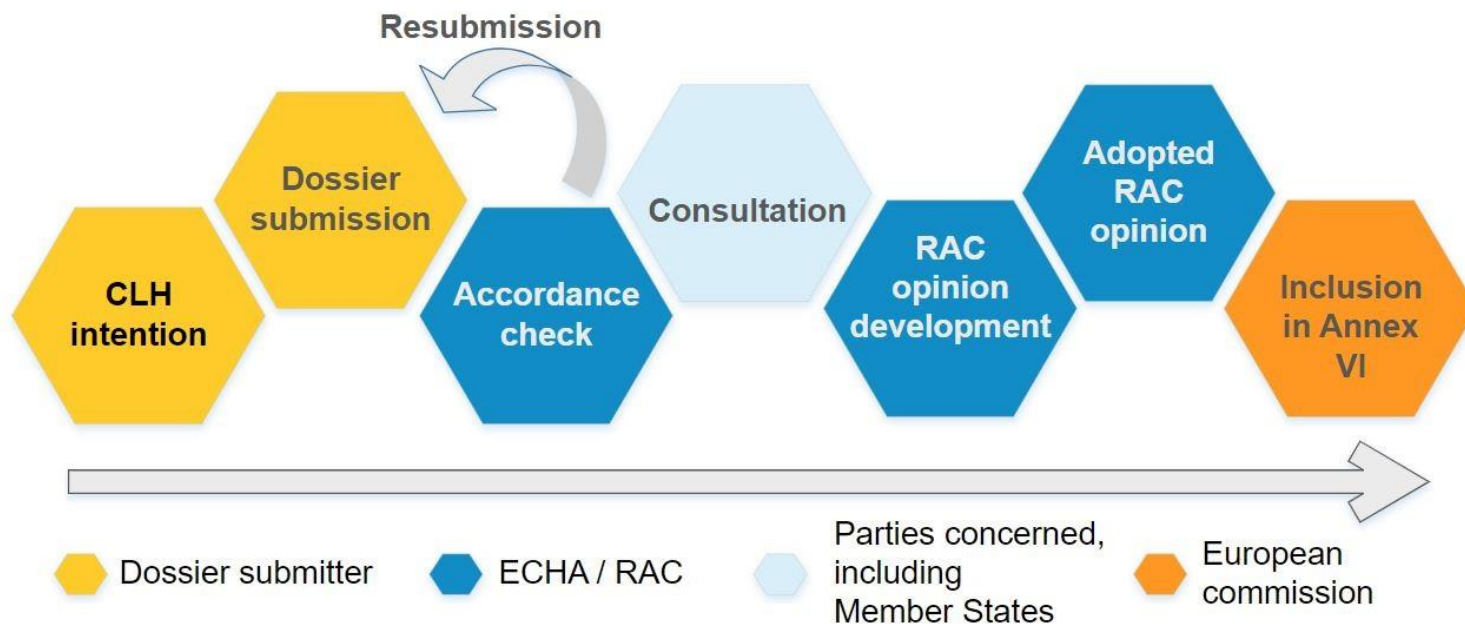
- Process proposals for harmonised classification and labelling (CLH)
- Ensure consistent, transparent, scientifically-robust and CLP-compliant proposals (accordance check)
- Support Member States and ECHA Risk Assessment Committee (RAC)
- Technical, scientific and administrative duties during process
- Support the European Commission in the decision-making process (post RAC) but also in case of an Appeal
- *Contribute to substance grouping and prioritisation*



# What isn't ECHA Secretariat's mandate under CLP (yet)

- Perform animal experiments/ test chemicals
- *Draft CLH proposals*
- *Influence which (groups of) substances will enter the process and when*
- *Impose which hazard classes will be subject to the CLH process*
- Dictate which classification is warranted
- Request generation of data
- Make decisions (only opinions!!)
- Risk assessment (only hazard identification, risk communication)

# CLH process



# CLH process in a nutshell

- Intention: Indicative date of dossier submission by MS/Industry
- Dossier submission: all available information to allow independent hazard assessment (CLH report and other support evidence)
- Accordance check: Editorial and scientific review of accordance with CLP requirements
- Consultation: 60-day consultation with interested parties and, subsequently, the dossier submitter
- Opinion adoption: By ECHA's RAC => Decision by the Commission, assisted by CARACAL

# ZeroPM Project: Prevention–Prioritisation-Removal

- Regulators (COM/ECHA) a bridge between Academia and Industry
- CLH process/ECHA a bridge between science and regulatory actions
- Synergies with Integrated Projects such as ZeroPM in
  - ✓ generating and compiling relevant hazard information (WP6, throughout)
  - ✓ identification and grouping of priority substances (WP5)
  - ✓ establishing safer alternatives (WP2) => minimise risk management actions
  - ✓ risk communication (WP2, WP4)
  - ✓ development of novel assessment tools (WP5, WP6)
  - ✓ support in an experts level



## New hazard classes for PMT/vPvM (and PBT/vPvB)

- 10/2020 Chemicals Strategy for Sustainability - towards a toxic-free environment
- Simpler one substance one assessment (1S1A) for chemicals risk and hazard assessment
- Assessment to gradually move from REACH (e.g. PBT assessment under REACH Article 57/ SVHC identification) to CLP (1S1A, CSS)
- CLP to be amended accordingly, two-stage process

# Application dates



# New hazard classes for PMT/vPvM (and PBT/vPvB)

## → Concern due to

- ✓ absence of other relevant Regulation
- ✓ difficult to break down, difficult to reverse accumulation in living organisms, long-range transport
- ✓ possibility to enter the water cycle, including drinking water
- ✓ only partial removal from wastewater treatment process
- ✓ ongoing emissions => build-up of environmental concentrations over time
- ✓ exposure of humans and the environment
- ✓ **=> protect the water resources**

# New hazard statements

| Hazard class and category code | Hazard statement code | Hazard statement   |
|--------------------------------|-----------------------|--|
| ED HH 1                        | EUH380                | May cause endocrine disruption in humans                                 |
| ED HH 2                        | EUH381                | Suspected of causing endocrine disruption in humans                      |
| ED ENV 1                       | EUH430                | May cause endocrine disruption in the environment                        |
| ED ENV 2                       | EUH431                | Suspected of causing endocrine disruption in the environment             |
| PBT                            | EUH440                | Accumulates in living organisms including in humans                      |
| vPvB                           | EUH441                | Strongly accumulates in living organisms including in humans             |
| 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 |



# Regulatory criteria for PMT/vPvM substances

| <b>Persistence</b>         | <b>P criteria</b>      | <b>vP criteria</b>     |
|----------------------------|------------------------|------------------------|
| <b>Medium</b>              | <b>Half-day (days)</b> | <b>Half-day (days)</b> |
| 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

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

**! NEW !**

| <b>Toxicity</b>    | <b>T criteria</b>                                      |                      |
|--------------------|--|----------------------|
|                    | <b>Exposure duration</b>                               | <b>Value (mg/L)</b>  |
| Ecotoxicity        | Chronic NOEC or EC <sub>10</sub>                       | <0.01                |
| Mammalian toxicity | <b>Endpoint</b>  | <b>Category</b>      |
|                    | 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           |

# Regulatory criteria for Mobility (M)

**Annex I: 4.4.2.1.2.** A substance shall be considered to fulfil the mobility criterion (M) when the  $\log K_{oc}$  is less than 3. For an ionisable substance, the mobility criterion shall be considered fulfilled when the lowest  $\log K_{oc}$  value for pH between 4 and 9 is less than 3.

**Annex I: 4.4.2.2.2.** A substance shall be considered to fulfil the 'very mobile' criterion (vM) when the  $\log K_{oc}$  is less than 2. For an ionisable substance, the mobility criterion shall be considered fulfilled when the lowest  $\log K_{oc}$  value for pH between 4 and 9 is less than 2.

*"The  $K_{oc}$  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".*

# Information to be considered

**Commission Delegated Regulation (EU) 2023/707, Annex I: 4.4.2.3.2.** The following information shall be considered for the assessment of M or vM properties:

- (a) results from adsorption/desorption testing;
- (b) other information, such as information from leaching, modelling or monitoring studies, provided that its suitability and reliability can be reasonably demonstrated.

**Annex I: 4.4.2.4.2.** In applying the WoE determination, the following information, in addition to the information referred to in Sections ... 4.4.2.3.2 ... shall be considered as part of the scientific assessment of the information relevant for the ... M, vM ... properties:

...(b) Information relevant for the M or vM properties:

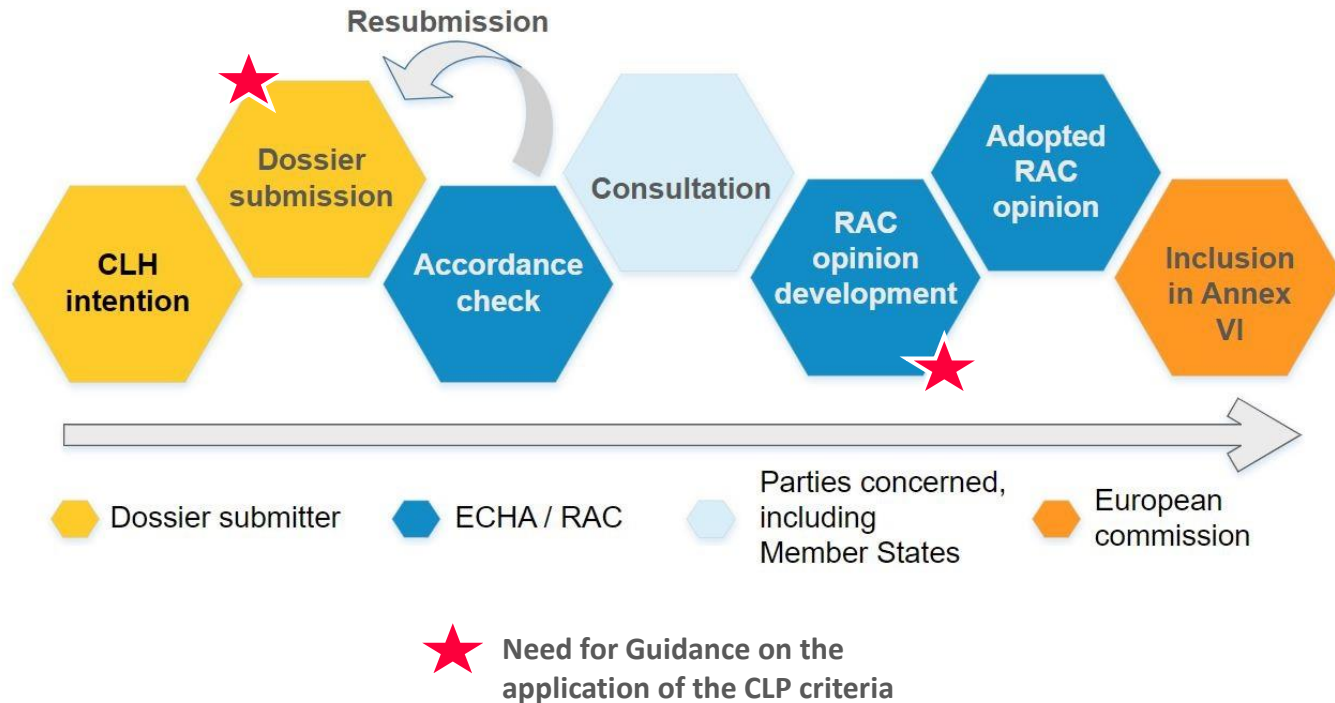
- (i) Organic carbon to water partition coefficient ( $K_{oc}$ ) estimated by well-developed and reliable (Q)SAR models;
- (ii) Other information, provided that its suitability and reliability can be reasonably demonstrated.

# Mobility (M) in a regulatory context

**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".*

- Log  $K_{oc}$  is a standard information requirement under REACH (Annex VIII) and BPR (Annex II)
- Mobility is a fairly novel hazard assessment index; limited experience on assessing Mobility under REACH and CLP
- Leaching studies under PPPR and BPR (risk assessment)

# Need for scientific Guidance



# Guidance development on the application of the CLP criteria

→ Current CLP Guidance includes:

- ❑ Physical hazards
- ❑ Health hazards
- ❑ Aquatic hazards
- ❑ Hazards to ozone layer



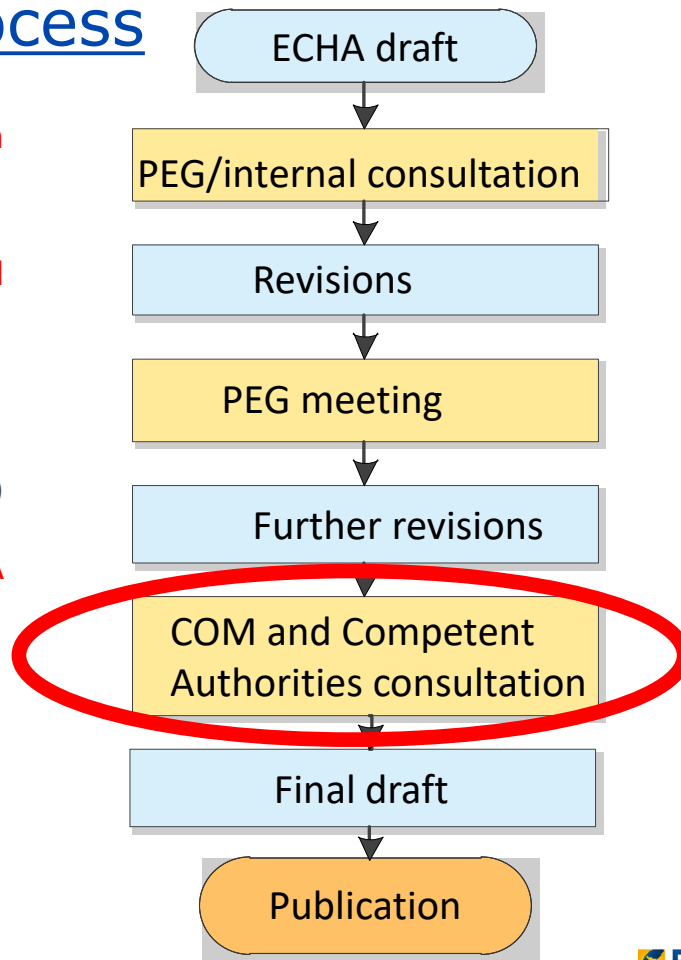
→ Guidance on the application of the **NEW** CLP criteria:

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



# CLP Guidance development process

- ❑ 12/2022: Establishment of internal **ECHA drafting team** and project co-ordinator
- ❑ Spring 2023: First discussions with **independent external experts**
- ❑ May 2023: **Ad-hoc PBT expert group**
- ❑ June 2023: Establishment of Partner Expert Group (PEG)
- ❑ September 2023: **Consultation with PEG and ECHA Committees**
- ❑ December 2023: **PEG meeting** (online)
- ❑ March 2024: **Revised draft to PEG**
- ❑ June 2024: **Consultation with CARACAL**
- ❑ Autumn 2024: Publication



# CLP Guidance structure

- Follows closely recently updated REACH PBT Guidance (R11)
- Introductory sections and definitions
- CLP criteria
- Relevant information and study considerations (as in the legal text)
  - ✓ experimental studies
  - ✓ field studies
  - ✓ QSARs and other modelling approaches
  - ✓ monitoring data
  - ✓ other lower-tier assessment elements



# CLP Guidance structure

- Assembly of information in a weight-of-evidence (WoE) determination to conclude per endpoint/property (i.e. P, vP, B, vB, M, vM, T)
- Application of the WoE to conclude on classification and labelling
- Provisions on dealing with multiple studies for same property
- Mixture classification criteria and hazard communication elements
- Examples (mainly from SVHC identification, more to come...)
- Guidance development an iterative exercise => update with experience and real cases

# Mobility (M/vM) assessment under CLP

## 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)
- ✓ Soil thin and thick layer chromatography (TLC)

**Commission Delegated Regulation (EU) 2023/707, Annex I: 4.4.2.3.2.** The following information shall be considered for the assessment of M or vM properties:

(a) results from adsorption/desorption testing;

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

**Annex I: 4.4.2.4.2.** In applying the WoE determination, the following information, in addition to the information referred to in Sections ... 4.4.2.3.2 ... shall be considered as part of the scientific assessment of the information relevant for the ... M, vM ... properties:

...(b) Information relevant for the M or vM properties:

(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

b) other information such as information from leaching, modelling or monitoring studies

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

# Elements to be considered for Mobility (M/vM) assessment under CLP

- Hazard vs risk assessment
- Data availability, reliability, relevance, (reducing) **uncertainty**
- Treatment of values close to regulatory thresholds and outliers
- Suitability of QSAR outcomes and modelling uncertainties
- Treatment of monitoring data
- Statistical distribution of data
- Pesticide-specific considerations and test methods/approaches

## Elements to be considered for Mobility (M/vM) assessment under CLP

- General preference on reliable outcome of OECD TG 106, but all relevant information considered within the WoE
- Assessment based on available information, no request of new data
- Engagement of **expert panels** early in the process essential
- Data on relevant constituents, additives or impurities of a substance and relevant transformation or degradation products
- Combination of several reliable study results conducted under the same test type and conditions may be possible, justification needed

## Mixture classification/ more than one constituents

- CLP Annex I: A mixture shall be classified respectively as a **X** when at least one component contained in the mixture has been classified respectively as a **X** and is present at  $\geq 0,1$  % (weight/weight)
- (New) Article 6: P, B or M only use data for each known constituent
- Data on the whole mixture can be used in certain cases, in particular when they demonstrate the P,B or M property
- Weight of evidence determination using expert judgement, weighing of all available information
- Derogation for substances extracted from plants

# 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:

<https://echa.europa.eu/support/guidance/consultation-procedure/ongoing-clp>

→ Process of first cases (2024)

→ Several MS intentions already logged

# Thank you, see you in September!!

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