German Environment Agency

Umwelt Bundesamt

Second ZeroPM Workshop

# A stepwise prioritization approach towards effective regulatory measures of PMT/vPvM substances in the REACH registration database

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50 Jahre Umweltbundesamt 1974–2024

# Prioritization …

… **enhances transparency and accountability** by providing
**a clear and documented process** for addressing chemical hazard and risk.

… **enables** regulatory authorities to target
the **most hazardous substances** and the **highest risky uses**.

… **ensures** that limited resources of regulatory authorities and industry stakeholders
are focused on the **most effective regulatory measure**.

… **encourages** innovation in the development of **safer and more sustainable** substances,
driving **economic growth and competitiveness** of EU industry on the worldwide market.

# Three steps to prioritize

- Step 1: **Identification**
  and classification of the intrinsic hazard
- Step 2: **Prioritization**
  of PMT/vPvM substances for regulation
- Step 3: **Prioritization**
  of regulatory measures based on their effectiveness

- Supported by a large research project funded by our Ministry
- Published 2023
- Press release 31/2023
  https://www.umweltbundesamt.de/en/press/pressinformation/water-resources-must-be-better-protected


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# Step 1: Identification and Classification of an intrinsic hazard

- Under REACH **the hazard data requirements** for a registered substance are triggered by the tonnage (tpa) and type of uses

- Three main types of information are requested:
  - Physical and chemical properties
  - Human health properties
  - **Environmental properties**

- **Self-classification** by manufacturer, importer and downstream user considers whether a substance or mixture displays properties that lead to a **hazard classification**

- Hazard classification is always the starting point for **exposure assessment** and **risk assessment** but also for **hazard communication**

Foto: Andre Bonn, Fotolia

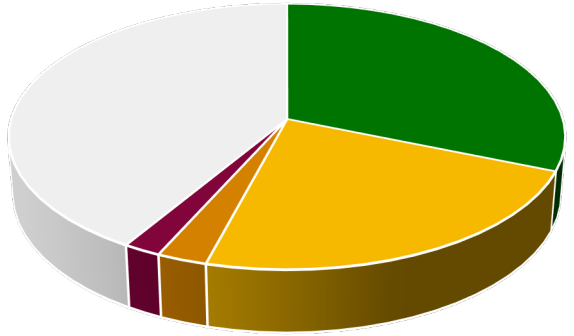
# New CLP hazard classes are in force in Europe

- **PMT** (persistent, mobile, toxic)
  - “Can cause long-lasting and diffuse contamination of water resources” (EUH450)
- **vPvM** (very persistent, very mobile)
  - “Can cause very long-lasting and diffuse contamination of water resources” (EUH451)
- **Self-classification** by manufacturer, importer, or downstream user with a long **transition period** until 2026
- **Harmonized classification** of PMT/vPvM substances by Member States and ECHA already scheduled and expected soon

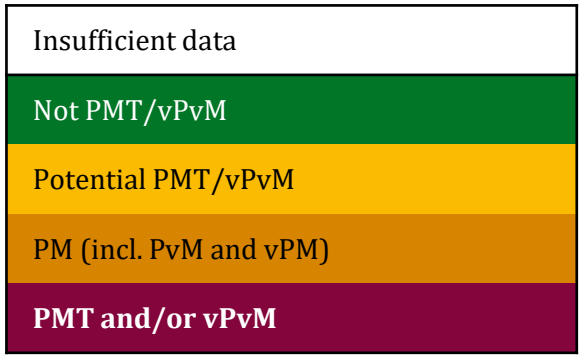
Foto: Zol, Fotolia

# PMT/vPvM substances in the REACH registration database

- With the support of the research project we were able to conduct **a PMT/vPvM assessment** for **the whole REACH registration database**
  - 31% did not meet the new PMT and vPvM hazard classes under CLP
  - For 64% no concluding PMT/vPvM assessment was possible either due to **missing test data** or due to **ambiguous assessment**
  - **only 1.9% (259 of 13,405) fulfil the new CLP criteria for PMT/vPvM substances**



13,405
unique chemical structures
in the
REACH registration database




[2] Arp & Hale (2023) (adapted to new CLP criteria)

# Step 2: Prioritization of PMT/vPvM substances for regulation

- Hazard classification is based on cut-off criteria,
  thus the **hazardous properties** themselves **<u>are not</u>** the basis for prioritization
- **Prioritization** is always based on **<u>external</u>** factors,
  like **emissions** or **exposure**, comparable to risk assessment
- **Prioritization** is also based on **<u>socio-economical</u>** factor**,**
  like if a PMT/vPvM substance is **<u>not</u> detectable** or **<u>not</u> removable**

Foto: antiksu, Fotolia

# The four prioritization criteria …

- … **use** a traffic light system to visualise available data and knowledge gaps (white colour)
- … **build** a prioritization framework for PMT/vPvM substances in the REACH registration database


[5] Arp et al. (2023) (adopted to new CLP criteria)

# PMT/vPvM substances prioritised for regulation

- Of the 259 PMT/vPvM substances in the REACH registration database **29 have the highest overall priority** for immediate regulatory action.
- **UBA selected** Melamine, Benzotriazole, 1,4-Dioxane, PFHxA and TFA.
- They are **ubiquitous detected in high concentration ,** have **very high emissions** and are **difficult to remove.**

| EC | CAS | Substance | Emission Likelihood | Exposure level | Analytical & Monitoring Gap | Remediation Gap |
|---|---|---|---|---|---|---|
| 203-615-4 | 108-78-1 | Melamine | very high | Ubiquitous, high conc | Monitored frequently | No O3&AC |
| 203-618-0 | 108-80-5 | cyanuric acid | very high | Ubiquitous, high conc | Minor monitoring gap | No O3&AC |
| 202-394-1 | 95-14-7 | Benzotriazole | very high | Ubiquitous, high conc | Monitored frequently | Both O3&AC |
| 204-661-8 | 123-91-1 | 1,4-dioxane | very high | Ubiquitous, high conc | Monitored frequently | No O3&AC |
| 244-479-6 | 21615-47-4 | Ammonium undecafluorohexanoate (PFHxA) | very high | Ubiquitous, low conc | Minor monitoring gap | No O3&AC |
| 200-929-3 | 76-05-1 | Trifluoroacetic acid (TFA) | very high | Ubiquitous, high conc | Monitored frequently | No O3&AC |
| 216-087-5 | 1493-13-6 | Trifluoromethane sulphonic acid | very high | Ubiquitous, high conc | Minor monitoring gap | No O3&AC |
| 249-616-3 | 29420-49-3 | PFBS | very high | Ubiquitous, low conc | Monitored frequently | No O3&AC |
| 201-132-3 | 78-67-1 | 2,2'-dimethyl-2,2'-azodipropiononitrile | high | no detections known | ot Monitored; analytical development feasibl | No O3&AC |
| 200-087-7 | 51-28-5 | 2,4-dinitrophenol | very high | Local, high conc | Minor monitoring gap | No O3&AC |

# Step 3: Prioritization of regulatory measures based on their effectiveness

- **Authorities** ensure that the **regulatory action** is targeted, effective and proportionate with an **Regulatory Management Option Analysis** (RMOA) as the final step in prioritization

- **Industry stakeholders**, ECHA and EU member states **are always involved** in the RMOA and the following **regulatory instruments under REACH & CLP** are assessed
  - CLP regulation
    - Harmonised hazard classification and labelling (CLH)
  - REACH regulation
    - Identification as substance of very high concern (SVHC)
    - Authorisation regime and inclusion in annex XIV of REACH
    - Restriction of certain uses

# Regulatory Management Options outside REACH & CLP …

- Industrial Emissions Directive (IED)
  - use of less hazardous substances and reduce releases of hazardous substances
- **Waste** Framework Directive
  - Directive on waste and repealing certain Directives
- POP Regulation
  - The Stockholm Convention on Persistent Organic Pollutants
- RoHS
  - restricting the use of certain hazardous substances in electrical and electronic equipment
- Food Contact Materials (FCM)
  - Regulation on material and articles intended to come into contact with food and repealing
- Voluntary Emission Reduction Measures taken by Industry
  - proactive approach of demonstrating safe use

# Past and Current Regulatory Activities for PMT/vPvM substances

- **PFHxA**
  - Proposal for Restriction for use in textiles and firefighting foams (submitted to ECHA 2019)

- **1,4-Dioxane**
  - Identification as SVHC in 2021
  - Proposal for Restriction 1,4-Dioxane content in detergents

- **Melamine**
  - Identification as SVHC in 2023
  - Proposal for harmonized classification as PMT, vPvM, Reproductive Toxicity

- **Trifluoroacetic Acid (TFA)**
  - Proposal for harmonized classification as PMT, vPvM,
    Repr. 1B Acute. Tox. 3, Skin Corr. 1A

- **Benzotriazole**
  - Proposal for harmonized classification as PMT, vPvM, ED ENV
  - Identification as SVHC (planned)

# Conclusion

- The implementation of **the PMT/vPvM criteria** into CLP and into REACH regulation is an essential step **to the protection of Europe´s drinking water resources**

- However: **64 % of REACH registered substances** have **missing or insufficient test data** for a conclusive PMT/vPvM classification => published as **UBA TEXTE 19/2023**

- Consequently: UBA will continue **to support REACH registrants** in identifying PMT/vPvM substances and **to close data gaps and non-compliance**

- Up today **only 1.9%** (259 of 13,405) fulfil the new CLP criteria for PMT/vPvM substances => published as **UBA TEXTE 21/2023**

- **The prioritization framework** indicates those PMT/vPvM substances that are in need of **immediate action** by REACH registrants and regulators => published as **UBA TEXTE 22/2023**

# Thank you for your attention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