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Aligning and Simplifying Chemical, Industrial Emission and Water Quality Regulations: Towards a Coherent EU Framework for Persistent, Mobile and Toxic (PMT) and very Persistent, very Mobile (vPvM) Substances

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Research Article

Keywords: Persistent, mobile and toxic (PMT) substances, very persistent and very mobile (vPvM) substances, CLP Regulation, REACH Regulation, Industrial Emissions Directive (IED), Water Framework Directive (WFD)

Posted Date: August 20th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-10549305/v1

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Additional Declarations: No competing interests reported.

Abstract

Background: Persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances threaten water resources when released in large volumes because they persist in the environment, spread readily through aquatic systems, and are difficult to remove once contamination has occurred. The introduction of the PMT and vPvM hazard classes under the Classification, Labelling and Packaging (CLP) Regulation represents an important step toward identifying PMT/vPvM substances, but effective environmental protection requires consistent regulatory advancements and alignments across related EU chemicals legislation to include these hazard classes. This paper examines how the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation, the Industrial Emissions Directive (IED), and the Water Framework Directive (WFD) currently regulate PMT/vPvM substances and identifies opportunities to strengthen the coherence of these legislative frameworks to protect water resources.

Results: The analysis shows that the current regulatory framework remains fragmented. Under REACH, PMT/vPvM substances can only be identified systematically through the resource-intensive equivalent level of concern clause, delaying risk management measures. Under the IED, emissions control largely depends on regulatory pathways established under REACH and the WFD. The WFD relies on monitoring data and established risk assessments that often fail to capture PMT/vPvM substances before widespread contamination occurs. The paper shows that systematically integrating the new CLP hazard classes into REACH, the IED, and the WFD would strengthen and simplify the links between hazard identification, chemicals management, industrial emissions control, and water protection.

Conclusion: Consistent implementation of the new CLP hazard classes in REACH, the IED, and the WFD would create a more coherent, simpler and preventive framework for minimizing emissions of PMT/vPvM substances to the environment. This would strengthen the EU's ability to prevent long-term contamination of water resources while supporting the objectives of the European Green Deal and the Zero Pollution Action Plan.

1. Background

Persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances pose a hazard to the environment (Neumann et al. 2015; Neumann and Schliebner 2019). Owing to their persistence and mobility in water, they can spread rapidly through aquatic systems and cause diffuse contamination of water resources. Their resistance to degradation and conventional treatment technologies makes remediation technically complex and costly, while effective exposure control after emissions have occurred is often not possible (Arp et al. 2024; Chirsir et al. 2024; Hale et al. 2022; Ling et al. 2026). This is especially relevant as, although current remediation technologies may enable the removal of PMT/vPvM substances, the effort required may be disproportionate to the quantities that can be removed, while novel substances entering the market may pose additional challenges (Hale & Arp, 2023). Moreover, the long-term effects of these substances are difficult to predict because environmental release and harmful impacts on ecosystems and human health may be separated by significant periods of time and geographical distance (Mohapatra and Hollender 2025).

The environmental and societal implications of a contamination of water resources with PMT/vPvM substances are substantial. Even if emissions cease, concentrations may remain elevated for long periods because of the persistent nature of these substances (Hale et al. 2020). PMT/vPvM substances therefore threaten drinking water resources and can impose considerable long-term societal costs (Hale et al. 2022). A relevant indication of the long-term societal costs associated with pollution by PMT/vPvM substances is provided by the European Commission’s estimate that contamination from per- and polyfluoroalkyl substances (PFAS), many of which (namely short-chain PFAS) are PMT/vPvM substances, could cost the EU approximately €440 billion by 2050 (European Commission et al. 2026). Regulatory responses often occur only after significant environmental damage has already taken place, particularly for persistent pollutants for which reductions in environmental burdens may only become visible over very long timescales (Conrad et al. 2021). This underscores the importance of preventive approaches that avoid emissions at source while complementing downstream monitoring and control.

The introduction of the PMT and vPvM hazard classes under the CLP (Classification, Labelling and Packaging; (EC) No 1272/2008 amended by (EU) 2024/2865) Regulation in 2023 represents a major regulatory development. Manufacturers and importers must self-classify substances according to these hazard classes from 1st November 2026, independent of their use. Substances

meeting the criteria may also become candidates for harmonized classification and labelling through inclusion in Annex VI to the CLP. Harmonized classification and labelling is applied case by case, typically where divergent self-classifications are identified, and therefore complements - rather than replaces - the need for accurate and consistent self-classification by industry. Statistics published by the European Commission already show manufacturers applying the new PMT/vPvM hazard classes in their own self-classifications (European Commission - a). The case of trifluoroacetic acid (TFA) and its inorganic salts represents a further milestone as the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) has adopted a harmonized classification of PMT/vPvM alongside reproductive toxicity category 1B (Committee for Risk Assessment 2026). As this is implemented by the European Commission, TFA will become the first substance included in Annex VI on the basis of the new PMT/vPvM hazard classes.

A classification into these hazard classes should have regulatory consequences beyond the CLP Regulation. Therefore, related EU legislation should be revised in a coordinated manner to incorporate the new hazard classes (Kättström et al. 2025). This paper focuses on the Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (REACH; Regulation(EC) No 1907/2006), the Industrial Emissions Directive (IED; Directive (EU) 2024/1785) and the Water Framework Directive (WFD; Directive 2000/60/EC). Together, these frameworks combine preventive measures, such as substitution and restriction under REACH, with control-oriented measures including emission limits under the IED and environmental quality standards (EQS) under the WFD (Mohr et al. 2024). This reflects the “toxic-free hierarchy”, which prioritizes preventing the use of PMT/vPvM substances over minimizing and controlling it, with remediation as the least desirable option (European Commission 2020; Hale et al. 2022).

Despite increasing scientific and political recognition of PMT/vPvM substances, the current approaches focus primarily on substances of very high concern (SVHC) and have not proven sufficiently proactive to prevent pollution caused by PMT/vPvM substances and their precursors and transformation products (Hale et al. 2022). More broadly, regulating chemicals on a substance-by-substance basis has been acknowledged as insufficient to achieve chemical safety and the EU's environmental objectives (European Commission 2020; Conrad et al. 2021; Santos et al. 2022; European Commission - b). A previous study identified 343 substances that met the PMT/vPvM criteria in the REACH registration database (Arp and Hale 2023), although this likely underestimates the true number because data gaps prevented conclusive assessment for approximately 67% of REACH registered substances (Arp and Hale 2023; Kättström et al. 2025). Only 122 of these substances are currently included in Annex VI to the CLP Regulation, none on the basis of their PMT/vPvM properties (see Additional file 1). While PMT/vPvM substances can in principle be addressed under REACH (Mohr et al. 2024), the IED and the WFD (Hale et al. 2022; Backhaus 2023), existing instruments across these three frameworks - including restrictions, authorizations, emission limit values and EQS - are not yet fully utilized. A more systematic and integrated approach is therefore needed to enable emissions to be minimized across legislative frameworks and to address legal gaps that hinder effective prevention and control (Conrad et al. 2021; Mohr et al. 2024).

This paper hypothesizes that consistent implementation of the new CLP hazard classes in REACH, the IED, and the WFD has substantial potential to reduce contamination of water resources with PMT/vPvM substances, thereby lowering societal costs and fostering chemical innovation towards safer and more sustainable chemicals. This work aims to identify legal gaps and opportunities for integrating the new PMT/vPvM hazard classes into these legislative frameworks following their introduction under the CLP Regulation. Building on this analysis, the paper develops proposals for strengthening coherence, including actions such as the explicit inclusion of PMT/vPvM properties in Article 57 of REACH, the consideration of these properties when setting emission limit values under the IED, and their integration into the prioritization criteria under Article 16 of the WFD. In doing so, this work contributes to the ongoing debate on how to operationalize the principle of prevention and strengthen the EU's capacity to address the long-term risks posed by PMT/vPvM substances.

2. Methods

This paper examines three legislative acts that represent different stages of the regulatory chain: REACH, the IED and the WFD (Fig. 1). REACH governs the registration, authorization and restriction of substances placed on the market and provides mechanisms for phasing out or strictly controlling SVHC (Regulation (EC) 1907/2006). The IED prevents and reduces emissions from industrial installations (Art. 1) through permit conditions, emission limit values and best available techniques (BAT) (European Commission 2019, 2021). The WFD structures the monitoring, prioritization and control of hazardous substances in surface water and groundwater, including through EQS and reduction or phase-out obligations (Art. 1(c), Art. 16 Directive 2000/60/EC). To support the analysis, a comprehensive literature search covering both policy documents (e.g., regulations, guidance documents, analyses,

and dossiers) and scientific literature was conducted using keywords including "persistent, mobile and toxic," "very persistent very mobile," "substance grouping," and "chemical regulation" in electronic databases such as PubMed and Google Scholar. The search was supplemented by backward citation searching of relevant publications to identify additional sources. By systematically combining database searches with reference list screening, a comprehensive body of literature relevant to the regulation of PMT/vPvM substances was compiled and considered in this paper. The analysis is based on the latest consolidated versions of REACH, the IED, and the WFD, accessed through the EUR-Lex database maintained by the Publications Office of the European Union. To identify provisions relevant to the new CLP hazard classes, the legislation was systematically searched using the terms "1272/2008," "hazardous," "classifi*," "persisten*," "mobile," and "toxic." To identify obligations specifically addressing PMT/vPvM substances, additional searches used the terms "PMT," "vPvM," "persist*," "mobil*," and "toxic" (see Additional file 2). The identified provisions were then examined in light of the paper's research question to assess whether and how the three legislative frameworks address PMT/vPvM substances and to identify regulatory gaps and opportunities for improved coherence. The policy-oriented analysis is situated within the objectives of the European Green Deal and the Zero Pollution Action Plan, which aim to reduce pollution of air, water and soil to levels no longer considered harmful by 2050 (European Commission 2019, 2021). Structurally, the paper examines the regulatory logic, gaps, and opportunities within REACH, the IED, and the WFD regarding PMT/vPvM substances, and develops recommendations for integrating the new PMT/vPvM hazard classes into these frameworks (Fig. 1).

During the preparation of this work, Large Language Model tools, including ChatGPT, Perplexity, and Claude, were used for language editing and proofreading purposes. All generated suggestions were critically reviewed and revised by the authors, who assume full responsibility for the content of this work.

3. Results

3.1. REACH: Regulatory logic

REACH (Regulation (EC) No 1907/2006) is the central EU framework for regulating chemicals and entered into force in 2007. It aims “to ensure a high level of protection of human health and the environment” from the risks posed by chemicals, based on the precautionary principle (Art. 1(1), 1(3)), while promoting innovation, competitiveness, and alternative non-animal testing methods (European Commission - c). A key feature of REACH is that manufacturers and importers are responsible for ensuring the safe use of chemicals (European Commission - c). Under the principle of “no data, no market” chemicals cannot be placed on the market unless they are registered with ECHA (Art. 5). Registration is required for substances manufactured or imported in quantities of one ton or more, per year, per company (Art. 6). Registrants must submit information on the substance's manufacture and identified uses, its classification and labelling, guidance on its safe use, exposure information, and when required under Article 14, a chemical safety report (Art. 10). ECHA and the Member States then evaluate the submitted information to determine whether additional regulatory action is necessary (European Commission - c).

Information requirements under REACH are tiered according to production or import volume. For substances produced or imported at 10 tons or more per year, registrants must prepare a chemical safety assessment and chemical safety report (Art. 14(1)) covering human health, physicochemical and environmental hazards, as well as a PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative) assessment (Art. 14(3)). Where a substance meets the criteria for certain physical, human health or environmental hazard classes under Annex I to the CLP Regulation - including explosive and flammable properties, acute and repeated toxicity, carcinogenicity, mutagenicity, reproductive toxicity, specific target organ toxicity, hazardous effects on the aquatic environment, or ozone depletion - or is identified as PBT or vPvB substance, the chemical safety assessment must also include an exposure assessment and risk characterization. PMT/vPvM substances are not, as such, covered by these requirements (Art. 14(4)) - though they may still fall within scope indirectly where their toxicity classification rests on CMR (carcinogenic, mutagenic or reproductive toxicity) properties. Following registration, authorities may conduct dossier evaluations (Art. 42) and substance evaluations (Art. 44). Substance evaluation follows a risk-based prioritization that considers hazard, exposure, and tonnage (Art. 44(1)), with substances that raise particular concern being placed on the Community rolling action plan (CoRAP), a three-year list of substances selected for in-depth assessment by Member State authorities or, where appropriate, ECHA itself (Art. 44–45). Evaluation may subsequently support regulatory measures, including the identification of SVHC or the initiation of restriction procedures (Art. 48).

The core regulatory mechanisms within REACH for managing SVHC are the SVHC identification, authorization and restriction processes. The authorization process is designed to control SVHC and gradually replace them with safer alternatives where technically and economically feasible (Art. 55). In contrast, the restriction process limits or prohibits the manufacture, placing on the market, or use of substances when they pose an unacceptable risk requiring action at EU level (Art. 68). Before a substance can be included in Annex XIV, it must first be identified as a SVHC under Article 59. A substance may be identified as a SVHC if it meets the criteria set out in Article 57, including classification as carcinogenic, mutagenic, or toxic for reproduction (category 1 or 2), PBT or vPvB properties, or if it is identified on a case-by-case basis under Article 57(f) as giving rise to "an equivalent level of concern" (Art. 57). This last category is especially important for PMT/vPvM substances: although they are not explicitly listed in Article 57, they have been recognized as presenting an equivalent level of concern to other SVHC classes - particularly PBT/vPvB substances - and may therefore still be captured under this provision (Hale et al. 2022). To date, PFBS, GenX, melamine and 1,4-dioxane have been identified as SVHC under Article 57(f) REACH on the basis that their PMT or vPvM properties pose an equivalent level of concern to PBT/vPvB substances and/or CMR substances (ECHA - a).

Once included in Annex XIV, the substance becomes subject to authorization, meaning that a company may not place it on the market or use it unless an authorization has been granted, an exemption applies, or the relevant transitional deadline has not yet expired (Art. 56). Prior to the decision to include a substance in Annex XIV, ECHA recommends prioritizing substances based on whether they are PBT/vPvB substances, substances in wide dispersive use, and/or substances with high volumes (Art. 58(3)). An authorization may be granted if the risk to human health or the environment is adequately controlled, or if the socio-economic benefits outweigh the risk and no suitable alternatives exist (Art. 60). Authorizations are time-limited, usually conditional (e.g., monitoring), and subject to review (Art. 60(8)), with substitution encouraged throughout the process (Art. 61(1)). Alternatively, where unacceptable risks are identified, restrictions may be adopted through amendments to Annex XVII (Article 68(1)). The procedure can be initiated by the Commission or a Member State through a dossier meeting the requirements of Annex XV (Art. 69). Both authorization and restriction therefore provide important mechanisms for managing PMT/vPvM substances once they have been identified under REACH as an SVHC.

3.2. REACH: Gaps and opportunities

Despite the broad scope of REACH, its current implementation reveals both significant gaps as well as opportunities for improving the management of PMT/vPvM substances. One of the most fundamental gaps is the insufficient data available to identify these substances. Although the PMT and vPvM hazard classes have now been introduced under the CLP Regulation, closing these data gaps will take time. As the hazard classes only entered into force in 2024, it remains to be seen whether the resulting exposure assessments and risk characterizations that become necessary will substantially improve the available data on PMT/vPvM substances. This is particularly important because REACH can only regulate substances that can be adequately identified and assessed. The new hazard classes can improve the identification of PMT/vPvM substances by making better use of existing information, while highlighting where important data are lacking. However, the CLP classification does not mandate the generation of new experimental data or automatically improve the quality of REACH registration dossiers. While manufacturers and importers may generate additional data to support self-classification, Member States preparing dossiers for harmonized classification have no legal mechanism to require further data where available evidence is insufficient. This limitation is particularly significant for PMT/vPvM substances, for which key information - especially on persistence - is often missing. Moreover, because the new hazard classes are being introduced gradually, (they apply immediately to substances first placed on the EU market from 1 May 2025, while substances already on the market must comply by 1 November 2026 and for mixtures, the corresponding deadlines are 1 May 2026 and 1 May 2028 (ECHA - b)) improvements in the availability of data will emerge only over time.

At the same time, the necessary amendment of Article 57 of REACH to explicitly include PMT/vPvM substances as SVHC, as envisaged in the Chemicals Strategy for Sustainability (European Commission 2020), has not yet been realized, leaving a misalignment between hazard identification under CLP and risk management under REACH. The absence of explicit PMT/vPvM criteria in Article 57 of REACH significantly hampers the systematic identification of such substances as SVHC, limiting rapid regulatory follow-up after Candidate List inclusion (Oules 2024). Identification and risk assessment is further complicated by UVCBs (unknown or variable composition, complex reaction products or biological materials), which may contain multiple constituents with PMT/vPvM properties or persistent and mobile transformation products (Hale et al. 2022). Data gaps, uneven data quality (Clara et al. 2022), and implementation deficits - including incomplete registration dossiers and safety data sheets -

further hinder the preparation of robust SVHC dossiers and demonstrate that existing legal obligations are not always effectively enforced (Conrad et al. 2021).

Beyond identification, the current risk-based paradigm under REACH presents inherent limitations for PMT/vPvM substances. The concept of "adequate control" is difficult to apply where emissions and environmental distribution remain uncertain over long time scales. In fact, it can be argued that there are no safe concentration limits for PMT/vPvM substances since any “[…] release of these substances into the environment throughout their lifecycle poses a risk for the environment” (Rose et al. 2022). Global recycling flows, changing use patterns, industrial accidents and climate-related events, including flooding, further increase uncertainty in exposure assessments (Hale et al. 2022).

REACH nevertheless provides several opportunities to address these shortcomings. A key step would be to amend Article 57 to explicitly include PMT and vPvM properties (Hale et al. 2020, 2022), enabling their systematic identification as SVHC and facilitating faster regulatory action through authorization and restriction (Oules 2024). The judgment of the Court of Justice of the EU confirming the identification of GENX as an SVHC (Case C-293/22 P 2023) provides an important legal precedent supporting the use of Article 57(f) for PMT/vPvM substances (Mohr et al. 2024). From a broader regulatory perspective, however, the interaction between REACH and the CLP Regulation should be revised to better integrate all new hazard classes (including endocrine disruption for human health and for the environment as well as PBT/vPvB substances) rather than focusing solely on PMT/vPvM substances. In addition, Annex XIII could be expanded to formally incorporate PMT/vPvM criteria (Arp and Hale 2023), building on assessment approaches developed by the German Environment Agency and supported by ECHA guidance (Hale et al. 2020).

Further opportunities lie in strengthening data generation and regulatory processes. While the CLP requires the self-classification of PMT/vPvM substances regardless of tonnage, REACH requires the generation of relevant data only above certain tonnage thresholds. Consequently, low-tonnage registrants are not required to generate key information such as the organic carbon-water partition coefficient (K_{OC}), which is essential for identifying PMT/vPvM substances. Lowering this threshold - for example, by requiring K_{OC} determination below 10 tonnes per annum through Annex VII rather than Annex VIII - would help close this gap and reduce the risk of low-tonnage PMT/vPvM substances currently being overlooked (Arp & Hale, 2023). Notably, recent discussions on the revision of REACH indicate that the EU is considering updating REACH registration data requirements to align them with the revised CLP Regulation and its new hazard classes, providing a timely opportunity to implement such changes (Council of the European Union 2026). Additional reforms could include extending the generic risk approach to the new CLP hazard classes by amending Annex I, point 6.5 to explicitly include the new hazard classes (Rose et al. 2022). In addition, Article 14(4) could be expanded to explicitly cover PMT/vPvM substances, requiring dedicated exposure assessments and risk characterization, while Article 68(2) could be amended to enable fast-track restrictions for consumer uses (Arp & Hale, 2023). Further suggested reforms include requiring dossier evaluations for all registrations (rather than only for a share of new registrations) and revising authorization and restriction procedures to improve efficiency and enforcement (Hale et al. 2022).

Identifying PMT/vPvM substances as SVHC could trigger downstream measures, including stricter emission controls under the IED and prioritization as well as monitoring under the WFD for substances posing risks to aquatic environments (Hale et al. 2022), as discussed further below. Finally, more systemic and preventive regulatory approaches could address structural weaknesses in the current system. As REACH is a cornerstone of EU chemicals regulation, its revision offers an important opportunity to strengthen upstream measures before widespread emissions occur (Hale et al. 2022). Group-based regulation could avoid slow, substance-by-substance decision-making and prevent regrettable substitution where a structurally similar PMT/vPvM substance from the same substance group replaces the initial problematic substance (Chirsir et al. 2024). The universal PFAS restriction and the restriction of PFAS in firefighting foams are clear examples of group-based regulation (European Commission 2025; ECHA - c). Together, these measures point towards a more anticipatory and integrated regulatory system better suited to the challenges posed by PMT/vPvM substances.

3.3. IED: Regulatory logic

The revised IED (Directive 2010/75/EU), as amended by Directive (EU) 2024/1785 entered into force in 2024 and aims to prevent and reduce emissions to air, water and land, as well as waste generation, from large industrial and livestock installations across the EU. It establishes a permitting system under which national authorities grant environmental permits (European Commission - d), requiring emission limit values that are set at the "strictest achievable" level by applying BAT, which are defined as the most environmentally effective and economically and technically viable means of preventing and controlling emissions (Art. 3(10)). The

strictest achievable limits are then based on an assessment of the entire range of the emission levels associated with BAT, with due regard to feasibility, the best overall environmental performance achievable by the installation, and possible cross-media effects (Art. 15(3)). The Directive applies to installations carrying out activities listed in Annex I, Annex Ia or in Part 1 of Annex VII that exceed specified capacity thresholds (Art. 3(3)). Its scope remains limited to emissions from such installations and does not extend to the placing on the market, use, or intrinsic hazard classification of substances, including PMT/vPvM substances. Instead, the IED provides a framework for pollution prevention and control based on permitting, BAT, and prevention principles (European Commission - d), covering key sectors such as the chemical industry, metal treatment, batteries, pulp and paper, and textiles (Annex I) which are all potential sources of PMT/vPvM substances, including many PFAS that likely meet the PMT/vPvM hazard criteria.

The IED is built on permits, which must include emission limit values, monitoring requirements and measures to protect soil and groundwater (Art. 14). Permit conditions are based on BAT conclusions derived from BAT reference documents (BREFs) (Art. 14(3)). They are periodically reviewed through an information exchange involving Member States, industry, civil society, the European Commission, and ECHA with the aim to focus on those BAT updates that have the highest potential to improve environmental and human health protection (Art. 13(1)). The IED defines hazardous substances by reference to Article 3 of the CLP Regulation (Art. 3(18)). As PMT and vPvM substances are now classified as hazardous under Article 3 of the CLP, they are consequently covered by the IED definition of hazardous substances.

This link is particularly relevant for Article 14, which sets out the core permit conditions. Article 14(1)(e) requires periodic monitoring of soil and groundwater "in relation to relevant hazardous substances likely to be found on site", thereby encompassing PMT and vPvM substances. The same connection is reflected in the requirement for operators to establish and maintain an Environmental Management System (EMS) as a condition for obtaining or maintaining a permit (Art. 14(1)(ba)). The EMS must include environmental objectives aimed at preventing or reducing hazardous substances, with particular attention given to substances meeting the criteria of Article 57 REACH and substances subject to restrictions under REACH Annex XVII. It must also contain a risk assessment of their impacts on human health and the environment and consider substitution with safer alternatives (Art. 14a(2)). Accordingly, the EMS also covers PMT and vPvM substances while strengthening the integration of the IED with REACH through its focus on SVHC and restricted substances.

By contrast, other key elements of Article 14 are not directly linked to hazardous substances. Most notably, Art. 14(1)(a) requires permits to include emission limit values for:

1. Substances listed in Annex II to Regulation (EC) No 166/2006, the predecessor of the IEPR (Industrial Emissions Portal Regulation (EU) 2024/1244).
2. Other polluting substances likely to be emitted in significant quantities, based on their nature, hazardousness, and potential for cross-media pollution transfer.

Article 15 of the IEPR empowers the Commission, by delegated act, to add substances to Annex II that are: listed under REACH (Annex XIV or XVII), designated as priority substances under the WFD and the Environmental Quality Standards Directive (EQSD, 2008/105/EC), included in relevant watch lists (Directive 2006/118/EC, 2008/105/EC, (EU) 2020/2184) or regulated under EU air and water quality legislation (Art. 15(2)(a) Regulation (EU) 2024/1244). However, such additions do not occur automatically: even where a substance meets these criteria, its inclusion in Annex II remains at the Commission’s discretion. PMT/vPvM substances may alternatively be regulated as "other polluting substances”. In this regard, the judgment of the Court of Justice of the European Union (Case C-626/22 2024) is particularly relevant, as it confirms that, when granting or reviewing an IED permit, the competent authority must take into account not only the pollutants normally associated with the activity, but also “[…] all those polluting substances which are the subject of emissions scientifically recognised as harmful […]” that may be emitted by the installation.

Article 14 further requires an assessment of the need to prevent or reduce emissions of SVHC under Article 57 REACH, or substances restricted under Annex XVII REACH (Art. 14(1)(ab)). This creates a potential pathway for PMT/vPvM substances, provided they have been identified as SVHC or are subject to restrictions. Article 14 also strengthens the link to water legislation by requiring Member States to consult the competent authorities responsible for EU environmental laws before granting a permit, including those authorities responsible for EQS values and limits (Art. 14(1)). Given that EQS values must be established for priority substances under the WFD, and PMT/vPvM substances may in principle qualify as such, this provision is noteworthy - even if substantial barriers to their designation as priority substances remain in practice (see Chap. 3.6).

3.4. IED: Gaps and opportunities

Important gaps remain in the IED regarding the regulation of PMT/vPvM substances. Primarily, emission limit values are unlikely to be set for these substances because Annex II of the IEPR does not explicitly include the PMT/vPvM hazard classes. Instead, it covers substances listed under REACH (Annex XIV or XVII) or priority substances under the WFD. However, as described in Chap. 3.2, REACH does not yet explicitly capture PMT/vPvM properties. Likewise, coverage under the WFD remains limited because prioritization relies on monitoring data and established risk assessments that are largely absent for PMT/vPvM substances, as discussed in more detail in Chap. 3.6. This illustrates a broader structural problem: both REACH and the WFD require resource-intensive, case-by-case assessments. Directly including PMT/vPvM substances in Annex II of the IEPR would significantly reduce the administrative burden. Although PMT/vPvM substances may also be addressed as "other polluting substances", this option likewise requires considerable administrative effort.

Beyond determining emission limit values, Annex II of the IEPR also determines which pollutants must be reported annually when emissions to air, water or soil exceed specified thresholds. Including PMT/vPvM substances in Annex II would therefore improve emission control as well as emissions monitoring and transparency. Reporting obligations could be extended to all substances identified as SVHC or restricted under REACH, thereby capturing PMT/vPvM substances falling within those categories. Alternatively, monitoring obligations could be linked to operators' existing self-classification obligations under the CLP Regulation. Where operators classify a substance used or produced at an installation as PMT or vPvM, emissions should be monitored and reported to the Industrial Emissions Portal where they exceed specified reporting thresholds. For individual PMT/vPvM substances that are already subject to regulatory obligations under EU legislation, and that have already been identified by the operator as PMT or vPvM substances - reporting thresholds comparable or toxicologically equivalent to those established for the long-chain PFAS PFOA and PFHxS (1 kg per year under Annex II of Regulation (EU) 2024/1244) could provide an appropriate reference point. As operators are already responsible for identifying these hazardous properties, extending this responsibility to emissions reporting would be both logical and proportionate while helping to address the current lack of emissions data needed for exposure assessments and future regulatory action.

The effectiveness of emission controls depends on BAT conclusions, yet the eight-year BREF review cycle (Art. 13(1)) risks delays in integrating emerging concerns. Additional opportunities arise from the interaction between the IED and REACH. Under the IED, the need to prevent or reduce emissions is currently assessed for SVHC identified under Article 57 of REACH or substances restricted under Annex XVII. Explicitly including PMT/vPvM properties in Article 57 of REACH would therefore have important legal consequences by requiring industrial operators to assess the prevention and reduction of emissions of these substances.

The upcoming review of Annex II of the IEPR, originally scheduled for December 2025 (Recital (29) of Regulation (EU) 2024/1244) and still pending at the time of writing, presents a valuable opportunity to reconsider the treatment of PMT/vPvM substances. The Commission will review the substances and thresholds in Annex II through a delegated act and assess whether thresholds for PFAS and other relevant substances should be lowered (Recital (29), Art. 15(3)). Consideration could also be given to amending Article 15 to provide for the systematic inclusion of substances with particularly concerning hazard properties, including PMT/vPvM substances, by reference to the CLP hazard classes. Such an amendment would ensure more systematic monitoring and reporting (Oules - a), generate data to support harmonization with downstream legislation such as the WFD, and improve the evidence base for more effective and cost-efficient risk management. Nevertheless, proposing amendments to the operative provisions of the IEPR at this early stage appears difficult given that the Regulation has only recently entered into force and no reporting cycle has yet been completed.

Recent Commission proposals to simplify environmental legislation (COM/2025/986 Final 2025) may further weaken this framework. The proposals would remove the requirement for the EMS to include a chemicals inventory, a chemical risk assessment, and an assessment of substitution possibilities for hazardous substances (COM/2025/986 Final 2025). The future of these requirements remains uncertain, as at the time of writing, the Council has proposed reintroducing the chemicals inventory and related assessment obligations (Council of the European Union 2026), while the European Parliament's rapporteur supports the Commission's proposal to remove them (Committee on the Environment, Climate and Food Safety 2026). Nevertheless, the EMS remains an important pathway for addressing PMT/vPvM substances through the CLP definition of hazardous substances while strengthening links with REACH by giving special regard to SVHC and substances subject to restrictions (Art. 14a(2)(d)). This link is particularly relevant because several PMT/vPvM substances have already been identified as SVHC. Repealing these EMS elements

would weaken mechanisms for identifying, assessing, and reducing hazardous substances, reduce transparency, limit the application of the precautionary and substitution principles, and make it more difficult for authorities to ensure effective prevention and control.

The 2024 amendment to the IED provided important opportunities by strengthening the link between the IED and REACH. ECHA now has a formal role in preparing and revising BREFs (Art. 13(1)), which could lead to greater consideration of PMT/vPvM substances, particularly once they are identified as SVHC under REACH. The strengthened links are also reflected in the new requirement for permits to assess the need to prevent or reduce emissions of SVHC (Art. 14(1)(ab)) and the link to REACH in Article 15 of the IEPR (Art. 15(2)(a) Regulation (EU) 2024/1244). Consequently, identifying PMT/vPvM substances as SVHC under REACH would have direct implications for their regulation under both the IED and the IEPR.

3.5. WFD: Regulatory logic

Since its adoption in 2000, the WFD (Directive 2000/60/EC) has been the central framework for water protection in the EU. In March 2026, the Council and European Parliament adopted Directive (EU) 2026/805, amending the WFD, updating the list of priority substances and introducing corresponding EQS or groundwater quality standards (Recital (13) Directive 2026/805). The Directive aims to achieve good chemical and ecological status for Europe's surface waters and groundwater while reducing and ultimately eliminating pollution. To this end, Member States must develop River Basin Management Plans and Programs of Measures to protect, improve and, where necessary, restore water bodies and prevent their deterioration (European Commission - e).

A core objective of the WFD is the "[…] enhanced protection and improvement of the aquatic environment, inter alia, through specific measures for the progressive reduction of discharges, emissions and losses of priority substances and the cessation or phasing-out of discharges, emissions and losses of the priority hazardous substances" (Art. 1(c)). Ultimately, the Directive seeks to eliminate emissions of priority hazardous substances and achieve concentrations in the marine environment close to natural background values for naturally occurring substances and to levels approaching zero for man-made synthetic substances (Art. 1(e)). The WFD primarily follows a retrospective regulatory logic, as priority is generally assigned to chemicals that have already been detected in the environment (Halbach et al. 2025). Regulatory measures are largely triggered by monitoring data (Reemtsma et al. 2016; Halbach et al. 2025).

Under the WFD, the control of chemical pollution is structured around three categories: *hazardous substances*, *priority substances* and *priority hazardous substances*. *Hazardous substances* are defined as substances that are toxic, persistent and liable to bioaccumulate, as well as other substances giving rise to an equivalent level of concern (Art. 2(29)). In principle, this definition can encompass PMT/vPvM substances because they may constitute substances of equivalent concern by accumulating in the water and exposure media (Hale et al. 2020). However, designation as a hazardous substance alone does not trigger substance-specific regulatory measures. Regulatory consequences arise only once substances are identified as *priority substances* under Article 16(2) and listed in Part A of Annex I to Directive 2008/105/EC (EQSD) (Art. 2(30)). Within this group, substances may subsequently be identified as *priority hazardous substances* under Article 16(3) (Art. 2(30a)).

Table 1
Overview of the Classification and Regulatory Consequences of Hazardous Substances under the WFD

Category	Legal basis	Definition	Regulatory consequence
Hazardous substances	Art. 2(29)	Substances that are toxic, persistent and liable to bioaccumulate, as well as substances giving rise to an equivalent level of concern.	No automatic EU-wide regulatory measures.
Priority substances	Art. 2(30), Art. 16(2),	Substances listed in Part A of Annex I to Directive 2008/105/EC (EQSD), that are substances which present a significant risk to or via the aquatic environment and are prioritized in accordance with Article 16(2).'	Progressive reduction of discharges, emissions and losses; establishment of EQS; implementation of Programs of Measures.
Priority hazardous substances	Art. 2(30a), Art. 16(3)	Priority substances which are identified as 'hazardous' in accordance with the legislation referred to in Article 16(3).	Cessation or phase-out of discharges, emissions and losses (where appropriate within 20 years); objective is the elimination of pollution.

The distinction between priority substances and priority hazardous substances determines the level of regulatory control. While the WFD defines priority substances (Art. 2(30)) and provides for their identification and prioritization (Art. 16(2)), the EQSD establishes the corresponding EQS (Art. 1 2008/105/EC). The Commission is to review the list of priority substances together with the corresponding EQS and, where appropriate, propose updates (Article 16(2)). Compliance with the applicable EQS for those priority substances forms part of the assessment of good surface water chemical status (Article 2(24)). Member States must implement Programs of Measures to progressively reduce pollution from priority substances (Art. 4(1)). Accordingly, the continued use of priority substances is permitted provided it is consistent with the Directive's environmental objectives and the measures adopted to achieve them. *Priority hazardous substances* are subject to a more stringent regime. Their discharges, emissions, and losses must be ceased or phased out, where appropriate within 20 years of designation (Art. 16(6)), reflecting the Directive's objective of eliminating, rather than merely reducing pollution from these substances (Art. 1(e)).

Priority substances are identified on the basis of their risk to, or via, the aquatic environment (see Table 1). The Commission relies on existing risk assessments under REACH and other sectoral legislation, including the Plant Protection Products Regulation (Regulation (EC) No 1107/2009), the Biocidal Products Regulation (Regulation (EU) No 528/2012) the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6), the Directive on Medicinal Products for Human Use (Directive 2001/83/EC), and the Directive on the Sustainable Use of Pesticides (Directive 2009/128/EC). Prioritization can also be based on a simplified scientific risk-based assessment, which considers the substance’s intrinsic hazard (especially aquatic toxicity and human toxicity via aquatic exposure routes), monitoring data showing widespread environmental contamination, and other indicators such as production/use volumes and usage patterns suggesting widespread pollution (Art. 16(2)). Key elements of the assessment include detailed data on the environmental concentrations of the substances, obtained through watch-list monitoring, as well as a thorough evaluation of their (eco)toxicological characteristics, as well as their persistence, bioaccumulation, mobility, carcinogenicity, mutagenicity, reprotoxicity, and endocrine-disrupting potential (Recital (12) Directive (EU) 2026/805). The list of priority substances is reviewed every six years (Art. 16(2)). During these reviews, the Commission classifies substances as priority hazardous substances, substances behaving like ubiquitous persistent, bioaccumulative and toxic substances, or substances tending to accumulate in sediment or biota (Art. 16(3)). In doing so, the Commission must consider substances of concern under other relevant Union legislation, including the CLP Regulation, relevant international agreements, and scientific reports. Particular attention must be given to substances meeting the criteria in Article 57 REACH where those criteria are relevant to the aquatic environment (Art. 16(3)).

3.6. WFD: Gaps and opportunities

The WFD presents several structural limitations in addressing PMT/vPvM substances. Although they could in principle qualify as "hazardous substances" under the equivalent-concern clause, this classification alone has no binding regulatory effect. Only formal designation as a priority substance triggers EU-wide measures - and this designation depends on risk assessments under the legislation referred to in Article 16(2) WFD and simplified risk-based procedures relying, among other factors, on monitoring data. The prioritization process therefore depends heavily on existing risk assessments and evidence of widespread environmental contamination, both of which remain limited for PMT/vPvM substances. Reemtsma et al. (2016) show that this reliance on monitoring data and established analytical methods has systematically led to the underrepresentation of highly polar and mobile substances among priority substances. Hale et al. (2020) similarly identify an "analytical gap" and a "monitoring gap" for highly mobile substances, meaning that many PMT/vPvM substances remain undetected, unmonitored and consequently unregulated. Since analytical methods are more readily available for non-polar and moderately polar compounds, currently regulated contaminants are concentrated in these categories, leaving highly mobile substances underrepresented (Reemtsma et al. 2016). Together, these gaps create a self-reinforcing cycle: limited monitoring data constrain prioritization, while the absence of prioritization reduces regulatory incentives to generate new data, reinforcing existing monitoring deficiencies and limiting the visibility of PMT and vPvM substances.

The prioritization criteria themselves are also poorly suited to PMT/vPvM substances. Although the WFD formally recognizes broader hazard properties, operational prioritization continues to rely primarily on comparing predicted no-effect concentrations (PNECs) with measured environmental concentrations (Halbach et al. 2025). Given the scarcity and often limited quality of monitoring data (Arp and Hale 2019), this approach cannot be meaningfully applied to many PMT/vPvM substances. This is problematic for PMT/vPvM substances, which travel large distances with water and are extremely difficult to remove once they reach groundwater and drinking-water resources. Waiting until monitoring demonstrates widespread contamination may therefore

mean that pollution has already become irreversible (Neumann and Schliebner 2019; Halbach et al. 2025). Risk-based approaches are further constrained by limited exposure and ecotoxicity data (Clara et al. 2022), while conventional PNECs may not sufficiently protect groundwater ecosystems because standard risk ratios can underestimate the hazards posed by PMT/vPvM substances (Di Cicco et al. 2024). Although non-target analysis could help address these data gaps (Clara et al. 2022), it has not yet been systematically integrated into the prioritization process. Monitoring also remains uneven across Europe and is often driven by universities, research institutes and, in some cases, drinking-water producers rather than by industry or regulatory authorities (Hale et al. 2022).

Several opportunities exist to address these limitations. Systematically considering the CLP hazard classes during the risk assessment under the prioritization process would facilitate the identification of PMT/vPvM substances as priority substances. This would trigger the obligation to implement measures pursuant to Article 4(1)(a)(iv), including the progressive reduction of pollution and to ensure applicable EQS under the WFD/EQSD framework. This does not imply that all PMT/vPvM substances should automatically be designated as priority substances; rather, PMT/vPvM properties should be taken more fully into account during the existing prioritization process. For those PMT/vPvM substances identified as priority substances, the pesticide limit of 0.1 µg/L could serve as a generic reference value, where substance-specific toxicological data are unavailable. Facilitating the identification as priority substances would also have important implications for their designation as priority hazardous substances, which are selected from among priority substances. Although the WFD already requires the CLP Regulation to be considered when identifying priority hazardous substances, this mechanism has little practical effect if PMT/vPvM substances are rarely prioritized in the first place.

Another step would be to strengthen data generation and monitoring by including PMT and vPvM substances in surface-water and groundwater watch lists, drawing on existing prioritization lists – such as the list of PMT/vPvM substances developed by the German Environment Agency across tonnage bands (Arp et al. 2022) - while also considering suspected PMT/vPvM candidates. Current watch-list selection under the EQSD primarily prioritizes substances requiring additional monitoring data, but for which sufficient toxicity information and suitable analytical methods already exist, and hazard properties are less important. Previous studies suggest that this approach could be strengthened by systematically considering intrinsic hazard properties, particularly persistence and mobility (Reemtsma et al. 2016; Halbach et al. 2025; Hartmann et al. 2026). Hale and Arp (2023) further observe that stronger regulatory drivers could increase demand for analytical methods and thereby stimulating their development, as monitoring incentives remain limited in the absence of legislative pressure.

Beyond improving monitoring, persistence and mobility could be integrated more systematically into the WFD framework. Halbach et al. (2025) propose building on Germany's Trace Substance Strategy, where persistence criteria are less stringent than under REACH, screening values may be accepted and additional reasons for concern may be considered, while assessing persistence and mobility in light of protecting groundwater, drinking-water resources, and aquatic ecosystems. This approach could build on existing practice by applying a generic threshold of 0.1 µg/L for those PMT/vPvM substances identified as priority substances unless lower values are justified, as already applied to pesticides. Updating the Technical Guidance Document for EQS to explicitly incorporate the PMT/vPvM hazard classes would further strengthen the WFD's objective of protecting water resources over the long term, facilitate the identification of priority substances, and help address existing monitoring deficiencies (Halbach et al. 2025). An appropriate opportunity for updating this document is provided by the Common Implementation Strategy Work Programme 2025–2027, which specifically aims to revise the technical guidance for deriving EQS (European Commission and DG Environment 2025).

4. Discussion

The introduction of the PMT and vPvM hazard classes under the CLP Regulation should be followed by corresponding amendments to REACH, the IED, and the WFD so that these new hazard classifications lead to consistent regulatory consequences throughout EU chemicals legislation (see Fig. 2). Without corresponding amendments to other legislation, the practical impact of the new CLP classifications will remain limited.

The most important step in this process is the explicit inclusion of PMT and vPvM properties in Article 57 of REACH. Rather than relying on Article 57(f) and the need to demonstrate an equivalent level of concern on a case-by-case basis, listing PMT/vPvM properties directly in Article 57 would enable their systematic identification as SVHC, accelerate authorization and restriction procedures, and facilitate their inclusion in the Candidate List (Oules - b). More broadly, REACH should be adapted to fully reflect the

new CLP hazard classes by extending the generic risk approach to PMT/vPvM substances and strengthening data generation, for example by amending REACH Annex VII to include the K_{OC} as a standard information requirement. Regulatory efficiency could also be improved by regulating scientifically justified groups of chemically or toxicologically related PMT/vPvM substances, rather than individual substances or all PMT/vPvM substances as a single group. This would accelerate regulatory action while reducing the risk of regrettable substitution, consistent with the existing grouping approach under REACH Annex XI, Section 1.5 (Chirsir et al. 2024).

These amendments to REACH would, in turn, strengthen industrial emissions control under the IED. Because the revised IED already assigns particular importance to substances identified under Article 57 REACH, the systematic identification of PMT/vPvM substances as SVHC would directly expand their consideration in industrial permitting, substitution assessments, and emission reduction measures (Oules - b). This effect could be reinforced by revising Article 15 of the IEPR to allow the systematic inclusion of all SVHC - or, alternatively, by directly referring to the PMT and vPvM hazard classes under the CLP Regulation when determining the substances listed in Annex II. Such amendments would ensure that SVHC and/or PMT/vPvM substances are routinely monitored, reported, and considered when establishing emission limit values. Since companies are already responsible for identifying substances with PMT or vPvM properties under the CLP Regulation, requiring them to monitor and report emissions of substances they use or produce that fall within these hazard classes would constitute a logical and proportionate extension of that responsibility. This would improve the availability of emissions data while addressing important information gaps for PMT/vPvM substances (Oules - a).

Improved emissions monitoring under the IED would also provide a stronger evidence base for water protection under the WFD. More comprehensive emissions data generated through the IEPR could complement existing monitoring data under the WFD. Further, the analytical standards and methods used as part of the emission monitoring could be used downstream by water authorities. At the same time, the WFD should systematically take the new CLP hazard classes into account when identifying priority substances. This would facilitate the identification of PMT/vPvM substances as priority substances, trigger the establishment of EQS and measures to progressively reduce their emissions, and, where appropriate, support their designation as priority hazardous substances, for which emissions must be ceased or phased out. In parallel, PMT/vPvM substances should be more systematically included in watch lists by giving greater weight to intrinsic hazard properties, particularly persistence and mobility, when selecting substances for monitoring. Together, these measures would strengthen data generation while shifting the WFD from a predominantly retrospective towards a more preventive regulatory approach.

Finally, once PMT/vPvM hazard classifications are systematically reflected across REACH, the IED, and the WFD, these legislative acts can reinforce one another through a continuous regulatory feedback loop. Hazard identification under the CLP Regulation should trigger risk management under REACH, which should subsequently initiate monitoring and emissions control under the IED. The resulting emissions data would support the implementation of more effective monitoring and prioritization under the WFD, while monitoring results generated under the WFD and emissions data reported through the IEPR should, in turn, systematically inform future authorization, restriction, and prioritization decisions under REACH. By integrating hazard classification, chemicals management, industrial emissions control, and water protection more effectively, the EU could improve the coherence and preventive capacity of the current regulatory framework, making it better equipped to address the long-term risks posed by PMT/vPvM substances, in line with the objectives of the Zero Pollution Action Plan (Oules 2022).

5. Conclusions

The introduction of the PMT and vPvM hazard classes under the CLP Regulation marks an important step towards improving the identification of substances that pose long-term risks to water resources and the environment. However, this work shows that the practical benefits of these new hazard classes will depend on whether they are systematically embedded across the wider EU chemicals regulatory framework. The consistent implementation of PMT/vPvM substances across these legislative frameworks would strengthen and simplify the link between hazard identification, chemicals management, industrial emissions control, and water protection. This would allow regulatory action taken under one framework to reinforce implementation under the others, resulting in a more coherent and preventive approach to managing PMT/vPvM substances.

Beyond the EU, the introduction of the new PMT and vPvM hazard classes into CLP has already sparked discussion on their potential inclusion in the UN Globally Harmonized System (GHS) (Sub-Committee of Experts on the Globally Harmonized System of

Classification and Labelling of Chemicals 2025). Extending these hazard classes to the GHS would ensure consistency in hazard communication globally, facilitate trade by avoiding discrepancies between regions, and streamline compliance for businesses operating in multiple jurisdictions. At the same time, it would support more consistent and effective risk management practices worldwide, thereby enhancing safety for workers, consumers, and the environment (Kättström et al. 2025).

Ultimately, the challenges posed by PMT/vPvM substances illustrate the importance of moving beyond fragmented regulation towards a more integrated system that reflects the interconnected nature of chemicals management and environmental protection. Ensuring their consistent implementation across EU legislation - and, in the longer term, potentially at the international level - would substantially improve and simplify the ability of regulatory frameworks to address substances whose persistence and mobility create environmental risks that are difficult, and often impossible, to reverse.

Declarations

Acknowledgements

Funding was provided by the European Union Horizon 2020 research and innovation programme under Grant Agreement No 101036756, ZeroPM. We would like to thank Stefan Kacan from the German Environment Agency for reading the manuscript and providing valuable feedback.

Ethics approval and consent to participate: Not applicable

Consent for publication: Not applicable

Availability of data and materials:

All data generated or analysed during this study are included in this published article and its supplementary information files.

Competing interests:

The authors declare that they have no competing interests.

Funding:

This work has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement N°101036756 from Oct. 2021 until Oct. 2026. More information can be found on www.zeropm.eu

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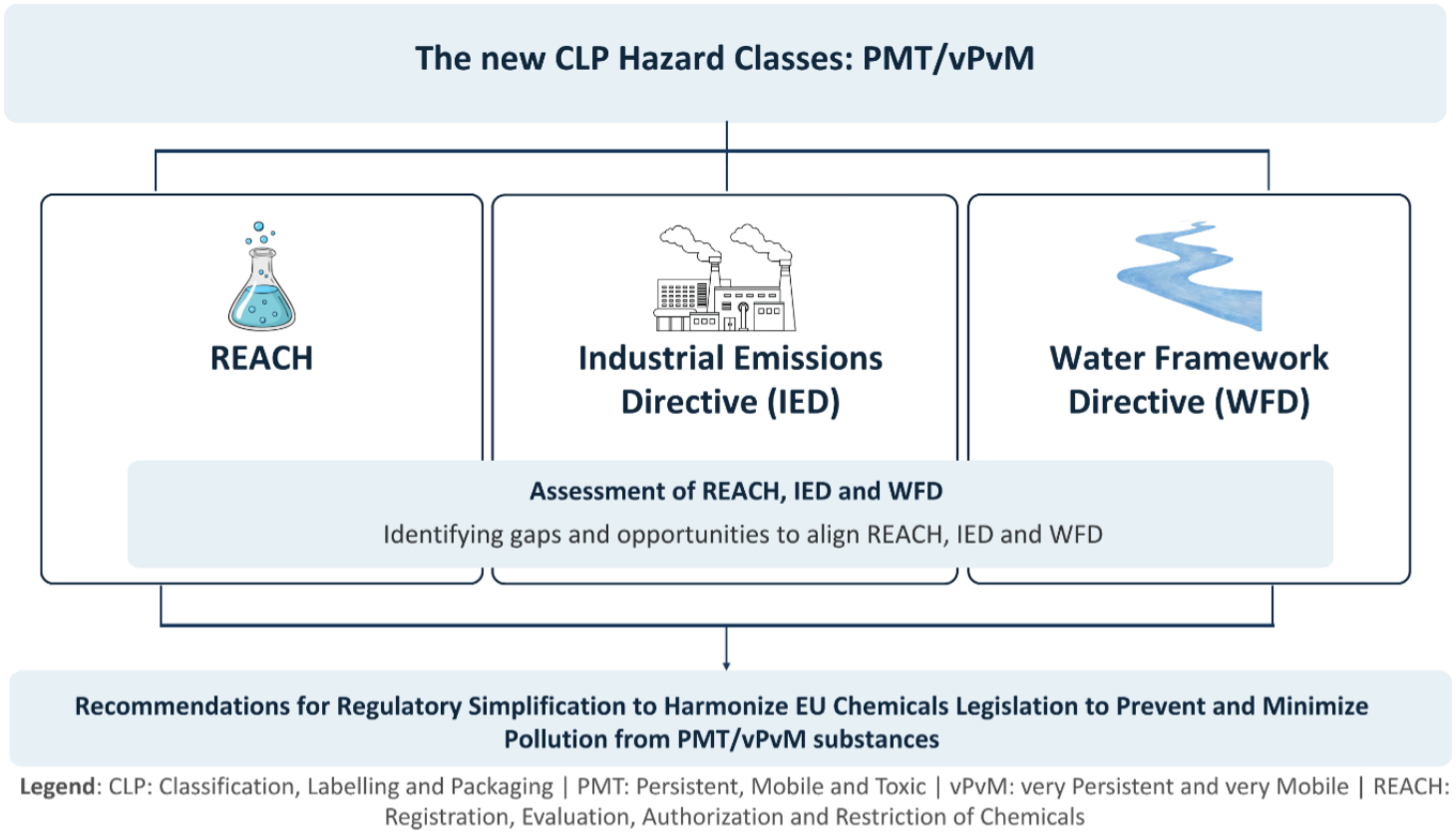
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Figures



Legend: CLP: Classification, Labelling and Packaging | PMT: Persistent, Mobile and Toxic | vPvM: very Persistent and very Mobile | REACH: Registration, Evaluation, Authorization and Restriction of Chemicals

Figure 1

Overview of the Assessment Approach. The new CLP hazard classes for PMT and vPvM substances require regulatory adjustments in REACH, the IED and the WFD. Each instrument is assessed for regulatory gaps and opportunities, from which recommendations for better alignment of EU chemicals legislation are derived. Figure created by the authors.

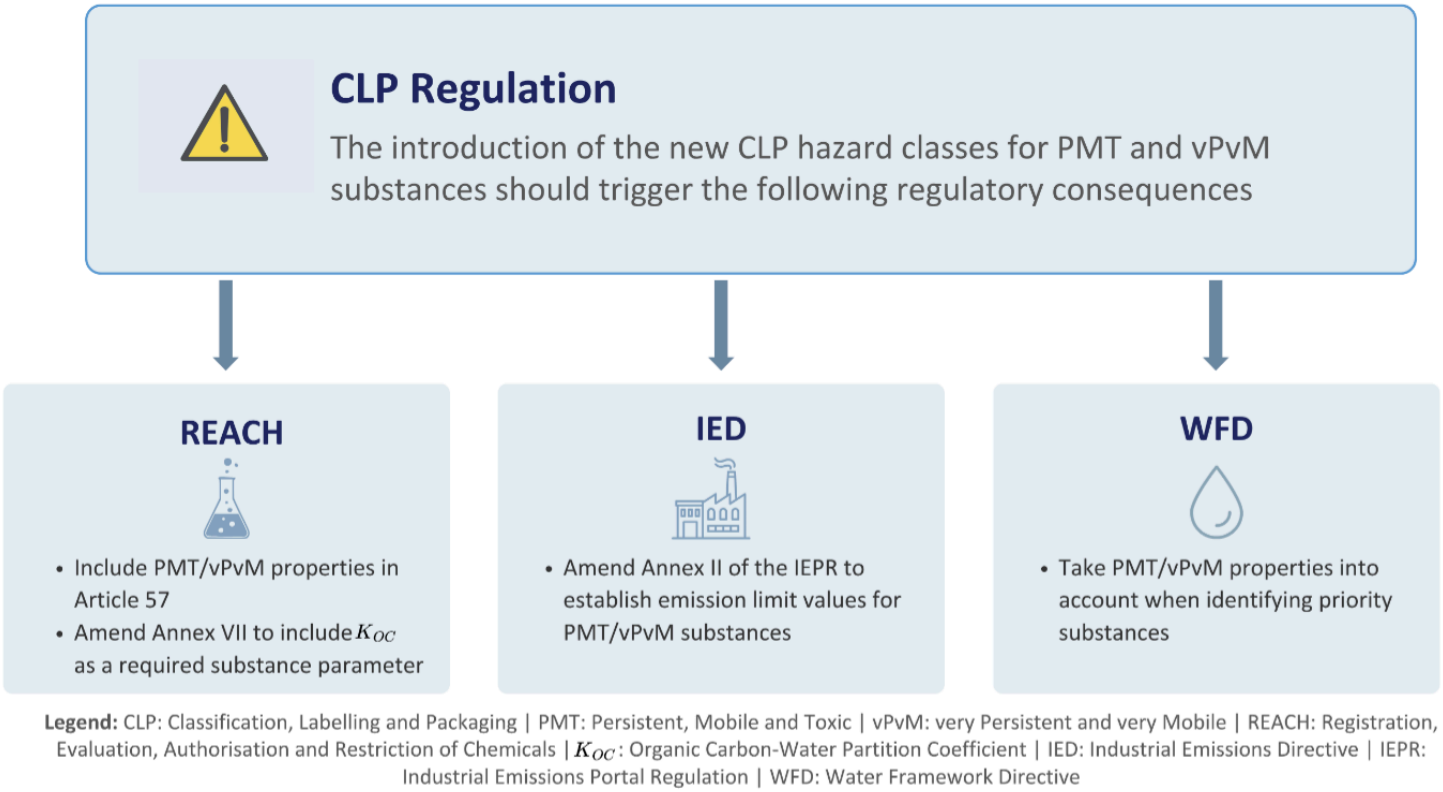


Figure 2

Proposed Amendments to REACH, IED and WFD. Proposed amendments include adding PMT/vPvM properties to Article 57 and K_{oc} to Annex VII of REACH, establishing emission limit values for PMT/vPvM substances in Annex II of the IEPR under the IED, and considering PMT/vPvM properties when identifying priority substances under the WFD. Figure created by the authors.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- AdditionalFile1ComparisonofUBAPMTvPvMlistandCLPAnnexVI.xlsx
- AdditionalFile2LegislationMatrix.xlsx