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REVIEW

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Progress in European chemicals policy to support the protection of the environment and human health from persistent, mobile and toxic and very persistent and very mobile substances

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Abstract

In 2020, the European Commission released its Chemicals Strategy for Sustainability towards a Toxic Free Environment (CSS) as part of the European Union's zero pollution ambition, which is a key commitment of the European Green Deal. One group of substances highlighted in the CSS is persistent, mobile and toxic and very persistent and very mobile (PMT/vPvM) substances. This article focuses on the current, broad European political landscape that applies to PMT/vPvM substances as well as looking into gaps and opportunities within this policy framework. To look at the political landscape, strategies and action plans published in the context of the European Green Deal, as well as a small number of other strategies adopted prior to the European Green Deal, were reviewed. A template was developed to identify actions related to PMT/vPvM substances and the actions were split between the following categories: "Prevent & Reduce", "Prioritize", and "Remediation". Following this, opportunities and gaps were identified. The current overarching strategy governing environmental policy is the European Green Deal which aims to achieve carbon neutrality and zero pollution by 2050. The CSS is the main and most focused Green Deal strategy addressing chemical pollution and uses a hierarchy tailored to chemicals management called the Toxic Free Hierarchy. The potential sources and exposure pathways of PMT/vPvM substances which result in environmental emissions are vast. This has the resultant effect that the relevant legal framework to address PMT/vPvM substances spans policies and legislation with different aims. Broadly, these policies and legislations are related to prevention, minimization/control and remediation, as reflected by the toxic-free hierarchy. There are many gaps and opportunities in the current policy framework which have primarily arisen due to the bold ambition of the CSS and the subsequent introduction of new hazard classes for PMT/vPvM substances. One such gap is related to a lack of harmonization across European Chemicals Policy demonstrated via the Cosmetics Regulation and the Biocidal Products Regulation (BPR) which are currently not aligned. The Cosmetics Regulation does not require a re-evaluation of a substance even in light of new scientific information, whilst the BPR requires new scientific evidence to be considered. In addition, REACH (SVHC criteria) and other legislation using hazard classes for triggering risk management measures (BPR, PPPR, pharmaceutical legislation, Water Framework Directive) may be expected to be revised or are currently being revised based on the new hazard class. The regulation of PMT/vPvM substances is in its infancy. While many EU action plans exhibit gaps

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and opportunities for chemical regulation as a whole, only certain policies refer to PMT/vPvM substances directly. It is up to policymakers, regulators and academia to highlight those gaps and corresponding emerging windows of opportunity that reflect potential regulatory engagement. The introduction of new hazard classes for PMT/vPvM substances in the Classification, Labelling and Packaging (CLP) regulation provides a first step as these substances are identified, however, regulatory consequences need to be implemented in all other legislation in the future. This will need strong commitment from the European Commission and the EU Member States.

Keywords Persistent, Mobile and toxic (PMT) substances, Very persistent and very mobile substances (vPvM), Classification, Packaging and labelling regulation (CLP), Registration, Evaluation, Authorisation and restriction of chemicals regulation (REACH), Essential use, Safe and sustainable by design (SSbD)

Background

In 2020, the European Commission released its Chemicals Strategy for Sustainability towards a Toxic Free Environment (CSS) which states "*Achieving a toxic-free environment requires more action to prevent pollution from being generated as well as measures to clean and remedy it*" [1]. Solutions to prevent manufacture, use or emissions of pollutants represent the most direct and efficient way to reduce exposure and contamination, and therefore, subsequent health, environmental management and removal costs. Figure 1 presents the toxic free heieracy for persistent, mobile and toxic and very persistent and very mobile (PMT/vPvM) substances. This is the first time such substances have been mentioned in European Chemicals Policy. PMT substances are defined in the Classification, Labelling and Packaging regulation as substances that "Can cause long-lasting and diffuse contamination of water resources" whereas vPvM substances are defined that those that "Can cause very long-lasting and diffuse contamination of water resources". Substances that are classified as vPvM but are also toxic would also be classified as PMT substances. However,

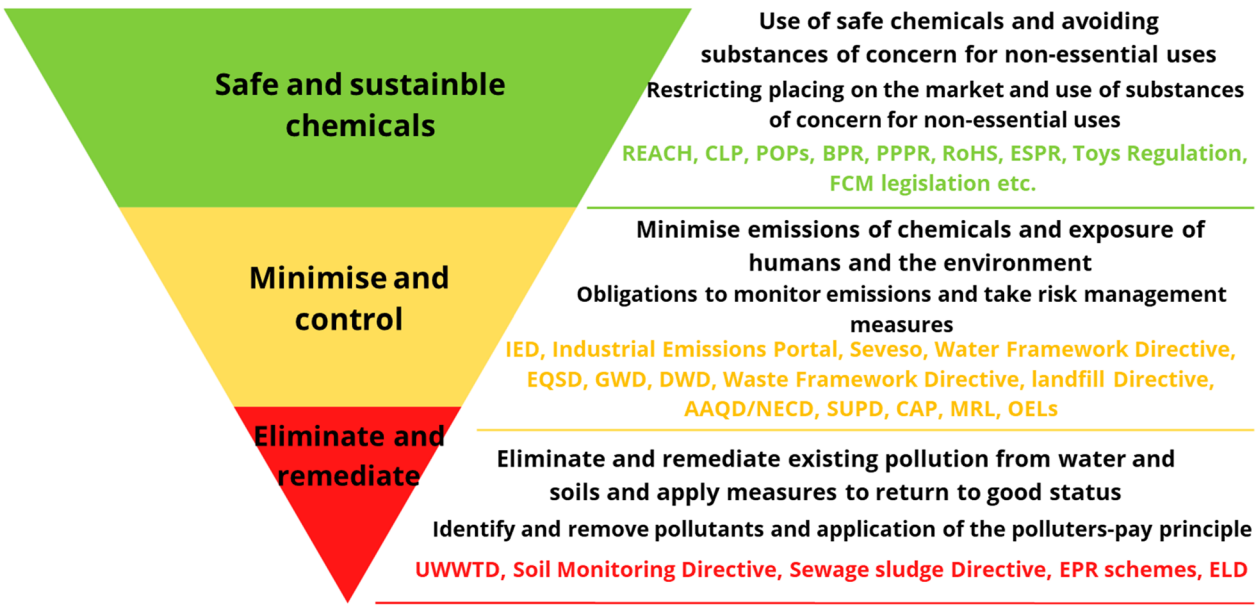

Fig. 1 The toxic free hierarchy and relevant legislations grouped according to the three categories. Black text provides details about the three categories and the coloured text below shows the legislations in the groups. Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) Regulation; Classification, Labelling, and Packaging (CLP) Regulation; Persistent Organic Pollutants (POPs) Regulation; Biocidal Products Regulation (BPR), Plant Protection Product Regulation (PPPR), Restriction of Hazardous Substances (RoHS), Ecodesign for Sustainable Products Regulation (ESPR), Food Contact Material (FCM) legislation; Industrial Emissions Directive (IED); Environment Quality Standards Directive (EQSD), Groundwater Directive (GWD), Drinking Water Directive (DWD), Ambient Air Quality Directive (AAQD); National Emission Ceilings Directive (NECD); Sustainable Use of Pesticides Directive (SUPD), Common Agricultural Policy (CAP), Maximum Residue Levels (MRL); Occupational Exposure Limits (OELs); Urban Wastewater Treatment Directive (UWWTD), Extended Producer Responsibility (EPR) schemes, Environmental Liability Directive (ELD). The toxic free hierarchy itself is taken from the CSS, while the text on the left is a paraphrasing of the hierarchy (black, bold text) and the list of legislations is added based on the work here (coloured text)

the very persistent and very mobile nature of vPvM substances is considered as sufficient grounds for regulation (and hence to vPvM hazard class in addition to the PMT hazard class). Owing to the enhanced possibility of the combination of these properties posing a threat to drinking water sources, as well as penetrating through natural and artificial barriers used in wastewater treatment [2]. The absence of the toxicity criterion on the vPvM classification is to indicate the enhanced probability of contamination and high removal costs, in the absence of toxicological or other impacts water quality (which may be known or unknown at the time of the vPvM classification). These substances do not degrade in the environment over appreciable timescales, do not adsorb to soil, particles and sediments and therefore can travel large distances in the aqueous environment, often breaking through natural and artificial barriers [3, 4]. These substances are not easily removed from wastewater, even by advanced remediation solutions, and as a result they can be found in the sources of drinking water [5, 6]. In addition, many of these substances are also toxic to the environment and human health [7].

The CSS proposes addressing these substances via revisions to chemicals policy, including the Classification, Labelling and Packaging (CLP) regulation and the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation, as well as by introducing new concepts, including "Essential Use" and "Safe and Sustainable by Design" (SSbD). In April 2023, the new hazard classes and criteria for PMT substances and vPvM substances came into force through the CLP regulation [8]. This article focuses on the current, broad political landscape that applies to PMT/vPvM substances in Europe as well as looking into gaps and opportunities within this policy framework.

Methods

The documents that were reviewed included strategies and action plans published in the context of the European Green Deal, as well as a small number of other strategies adopted prior to the European Green Deal (such as the Plastics Strategy). The full list of documents reviewed is as follows: Biodiversity Strategy (COM(2020) 380 final), Chemicals Strategy for Sustainability (COM(2020) 667 final), Circular Economy Action Plan (COM(2020) 98 final), European Green Deal (COM/2019/640 final), Europe's Beating Cancer Plan (COM(2021) 44 final), Farm to Fork Strategy (COM(2020) 381 final), Industrial Strategy for Europe (COM(2020) 102 final and COM(2021) 350 final), Pharmaceutical Strategy (COM(2020) 761 final), Renovation Wave for Europe (COM(2020) 662 final), Soil Strategy for 2030 (COM(2021) 699 final), Strategy for Plastics in a Circular Economy (COM(2018) 28 final), Sustainable Blue Economy Strategy (COM(2021) 240 final), Sustainable and Circular Textiles Strategy (COM(2022) 141 final), Zero Pollution Action Plan (COM/2021/400 final) and SWD 'Towards a monitoring and outlook framework for the zero pollution ambition' (SWD(2021) 141 final). A template was developed to identify actions related to PMT/vPvM substances. Specifically, the actions were split between the following categories: "Prevent & Reduce", "Prioritize", "Remediation" (and "Other") and sub-categories (research and development; policy realignment; tightening and reformation of relevant legislation; raising awareness (towards consumers and non-consumers); stakeholder cooperation; financing). Following this, opportunities and gaps were identified.

PMT/vPvM substances in European chemicals policy

To identify where PMT/vPvM substances fit into current EU chemicals policy, it is first important to review the relationship between the EU's Green Deal, Zero Pollution Action Plan and the CSS [1, 9, 10]. The European Green Deal is the current overarching strategy governing environmental policy and it aims to achieve carbon neutrality and zero pollution by 2050. To achieve this goal, the Green Deal provides a holistic policy framework to transform the economy towards increased sustainability, addresses pollution from chemicals and environmental degradation by means of prevention and remediation, and seeks to establish and develop sustainable value chains. In this regard, the Green Deal introduces the Zero Pollution Ambition for a toxic free environment, which focuses on chemical pollution, preserving and restoring ecosystems and biodiversity, as well as mobilising industry for a clean and circular economy. The Ambition is translated in to the Zero Pollution Action Plan which sets the general target to achieve zero pollution by 2050, when '*air, water and soil pollution is reduced to levels no longer considered harmful to health and natural ecosystems and that respect the boundaries our planet can cope with*' [10]. In addition, the Green Deal also announces the CSS *"to ensure a toxic-free environment".* Zero pollution in its literal sense would mean that concentrations of all pollutants are reduced to zero. This is not practical, and it is more likely that the terminology is an ambition to strive for.

The CSS is the main and most focused Green Deal strategy addressing chemical pollution and is organised around two main objectives. The first is shifting production towards chemicals that are safe and sustainable by design and the second is addressing environmental and health concerns of chemicals, by, amongst other measures, strengthening the legal framework to achieve zero chemical pollution in the

environment. It should be noted that the CSS itself is not a legally binding document. The CSS uses a hierarchy tailored to chemicals management called the Toxic Free Hierarchy [1]. The hierarchy places the development of safe and sustainable chemicals, clean production and recycling processes and the phase out of substances of concern for non-essential uses at top priority. At second priority, minimisation and control efforts are sought that are directed towards risk management measures achieved through the promotion of modern and smart production processes and safe and sustainable uses and business models. The final priority choice in the hierarchy is the elimination and remediation of pollution in environmental media, waste and secondary raw materials. Figure 1 presents the toxic free hierarchy as well as the enabling legislations that were considered at the time of writing to be the ones most relevant for PMT/vPvM substances.

One group of persistent substances the CSS places a special emphasis on is per- and polyfluoroalkyl substances (PFAS), coined Forever Chemicals owing to their extreme persistence [11, 12]. The Essential Use concept and how it applies to substances like PFAS is a central part of the CSS. Currently the definition of Essential Use is designed to ensure the '*most harmful chemicals*' are only allowed if '*their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health*' [1]. This definition is currently under discussion [13]. To transition away from non-essential uses of such substances, the EU will promote and reward the production and use of safe and sustainable chemicals and incentivize innovation and substitution of substances of concern. By 2030, clean chemicals value chains should be achieved where '*chemicals are produced and used in a way that maximises their contribution to society, including achieving the green and digital transition, while avoiding harm to the planet and to current and future generations*' [1].

The CSS, the Zero Pollution Action Plan and the Circular Economy Action Plan place a strong focus on developing the circular economy through '*toxic free material cycles*' and clean recycling. This is an important driver in the Green Deal strategies for the substitution of hazardous substances in products and their removal in recycled materials. The CSS plans for the development of SSbD criteria for chemicals and materials, which will provide guidance for assessing the safety, sustainability and circularity of products and processes in an integrated way and through their lifecycle, from design stages to end of life and reuse or recycling [1].

Regulatory measures for PMT/vPvM substances

From a regulatory perspective, the hazard caused by persistent and mobile substances was first broached by the German Environment Agency (UBA) in 2009 [14] and further developed into a regulatory concept under REACH [15, 16]. Since 2009, extensive effort has been placed on the consultation and the scientific, technical and regulatory development of the PMT/vPvM criteria [4, 17, 18]. As a consequence, in April 2023, the new hazard classes PMT and vPvM came into force under the CLP regulation. The introduction of new hazard classes for PMT/vPvM substances in the CLP regulation is expected to present subsequent consequences for other areas of legislation. For example, Article 3 [18] of the Industrial Emissions Directive defines the term "*hazardous substances*" according to the standards already set in Article 3 of the CLP Regulation. Article 3 refers to Annex I of the CLP Regulation for "*Classification and Labelling requirements*", which in turn contains information about hazard classes and their corresponding criteria [19]. Therefore, the new harmonised classifications for PMT/vPvM substances and changes to Annex I of the CLP regulation may increase the number of site operators requiring permits under the Industrial Emissions Directive related to monitoring and controlling these substances. Similar changes may be expected for other regulations already containing exclusion criteria based on hazard classes (currently mainly CMRs), such as the Biocidal Product Regulation, Plant Protection Product Regulation. Prior to the introduction of the new hazard classes, there was no form of harmonized regulation for PMT/vPvM substances. Instead, individual PMT/vPvM substances could be identified as substances of very high concern (SVHC) under REACH on a case-by-case basis using Article 57 (f). Article 57 (f) allows the inclusion of a substance in the list of SVHC if scientific evidence can be presented on effects that demonstrate serious harm to human health or the environment, in the form of an "*equivalent level of concern*" as a substance demonstrating carcinogenic, mutagenic, reproductive toxicant or PBT/vPvB substance properties [20]. This clause may be relevant for persistent substances that adsorb to soils or sediment and thus remain in this environmental compartment. To date, this Article has been used to identify melamine, 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propionic acid (GenX), its salts and its acyl halides, 1.4-dioxane and perfluorobutane sulfonic acid (PFBS) and its salts as SVHC based on their PMT/vPvM properties. The identification of GenX as a SVHC was challenged by the chemicals company Chemours, however, in November 2023, the Court of Justice of the European Union ruled against Chemours upholding the identification by the European Chemicals Agency [21]. This Court

Ruling demonstrates the legal support for the potential identification of PMT/vPvM substances as SVHC, with GenX as the case in point.

The legal framework for PMT/vPvM substances

The legal framework for PMT/vPvM substances considers potential sources and exposure pathways for PMT/vPvM substances to the environment (see Fig. 2) based on the deleterious socioeconomic impacts of their emissions into the environment [2]. The potential sources and exposure pathways of PMT/vPvM substances which result in environmental emissions are vast. They can include both point and diffuse sources that span multiple pathways across the complete life cycle of the substance, covering manufacture, use, disposal and recycling. Emissions can arise from industrial manufacturing and use in products or processes which then result in direct emissions to humans and the environment (e.g. pharmaceutical and personal care products (PPCP) and agricultural chemicals). Waste management infrastructure encompassing landfills, incineration plants and wastewater treatment plants (WWTP) as well as any contaminated biosolids produced then applied to agricultural land may also be a source of emissions and exposure routes. These direct and indirect emissions result in the contamination of air, soil, sediment, surface water, groundwater and drinking water supplies. Given that PMT/vPvM substances are difficult and costly to remove from water

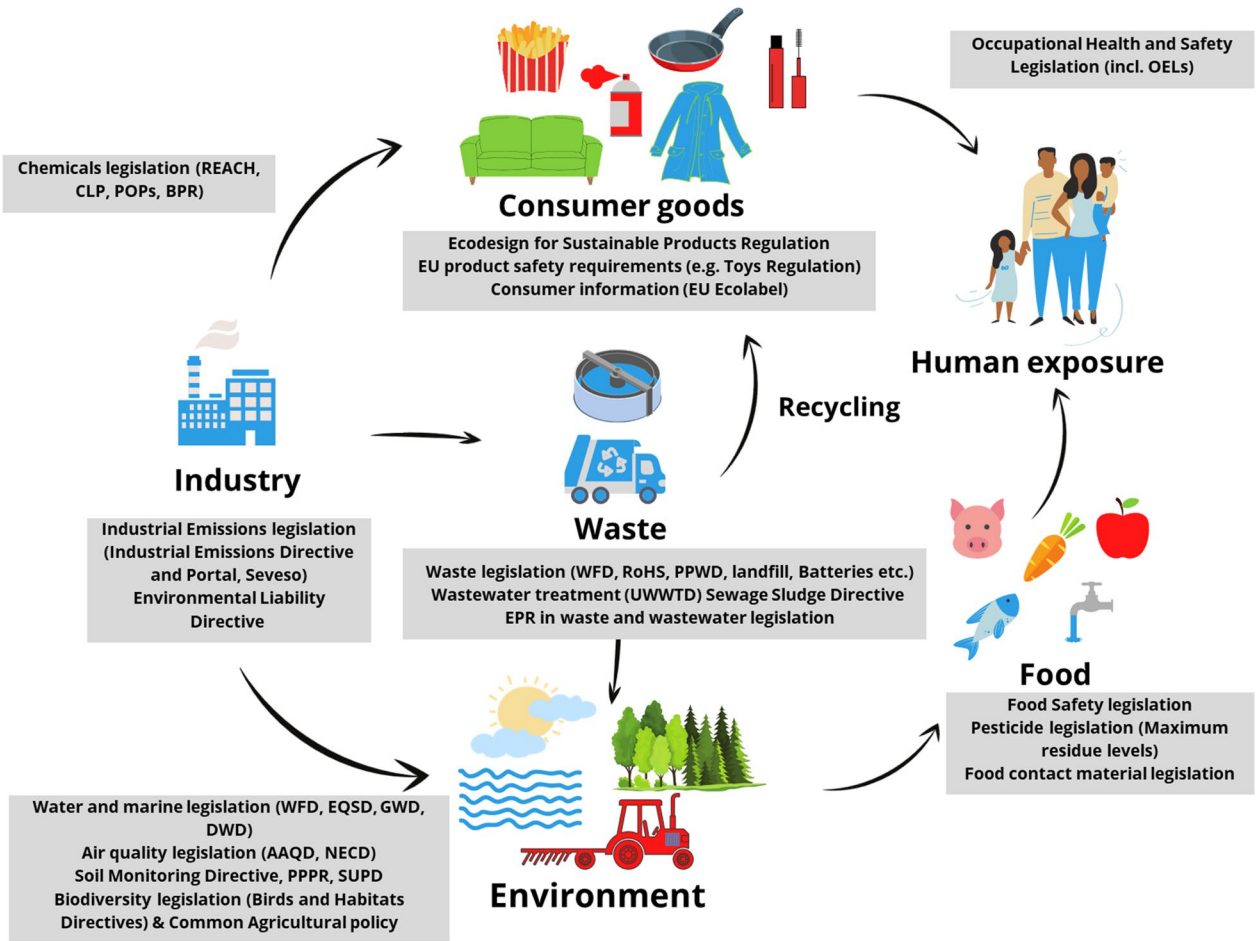

Fig. 2 Conceptual illustration of relationship of relevant policy areas for PMT/vPvM substances. Figure is based on a similar figure in a report published by the European Environment Agency in 2019 [23] but adapted for PMT/vPvM substances. REACH = Registration, Evaluation, Authorisation, and Restriction of Chemicals Regulation; CLP = Classification, Labelling, and Packaging Regulation; POPs = Persistent Organic Pollutants Regulation; BPR = Biocidal Products Regulation; WFD = Waste Framework Directive, RoHS = Restriction of Hazardous Substances Directive; PPWD = Packaging and Packaging Waste Directive; UWWTD = Urban Wastewater Treatment Directive; EPR = Extend Producer Responsibility; WFD in the water and marine legislation box = Water Framework Directive; EQSD = Environment Quality Standards Directive, GWD = Groundwater Directive; DWD = Drinking Water Directive; AAQD = Ambient Air Quality Directive, NECD = National Emission Ceilings Directive; PPPR = Plant Protection Product Regulation; SUPD = Sustainable Use of Pesticides Directive

resources, they can consequently circulate in drinking water cycles when wastewater re-enters drinking water extraction points [22].

Based on the exposure sources and pathways described above, the relevant legal framework to address PMT/vPvM substances spans policies and legislation with different aims that are broadly related to prevention, minimization/control and remediation, as reflected by the toxic-free hierarchy (Fig. 1). Policies that are related to prevention include those encouraging the replacement of PMT/vPvM substances with safer and more sustainable substitutes. To this end, requirements for registrants registering a new chemical or product could include a requirement for accompanying analytical methods to detect and measure these substances in media at environmentally relevant concentrations. To do so would facilitate effective monitoring, early detection, and proactive preventative actions. This can be achieved by authorizing or restricting their manufacturing for certain uses or products, by enabling policies based on the polluter pays principle or by requiring industrial facilities or other sectoral activities to take preventive measures against pollution. Directives or regulations that are relevant include REACH, the Industrial Emissions Directive, the Plant Protection Product Directive and the Biocidal Products Regulation, to name a few. Policies that encourage minimization and control include those setting emission limits, concentration limits and environmental thresholds, such as the Water Framework Directive, Drinking Water Directive and Groundwater Directive. Policies related to remediation include those establishing rules for the collection, treatment, reuse, recycling, decontamination and disposal of certain types of waste. Relevant directives here include the Urban Wastewater Treatment Directive, Sewage Sludge Directive, or product specific directives related to toys and food packaging materials. Figure 2 shows the most relevant policy areas at the time of writing to address PMT/vPvM substances grouped according to exposure sources and pathways.

There are several EU strategies that do not directly focus on chemicals, but where PMT/vPvM substances are relevant as there are many pesticides, biocides, pharmaceuticals, cosmetics, food contact materials and fertilizers that contain PMT/vPvM substances [24]. The Biodiversity Strategy [25] identifies pollution as a key driver of biodiversity loss and indicates that the following pressures must be reduced: '*the release of nutrients, chemical pesticides, pharmaceuticals, hazardous chemicals, urban and industrial wastewater, and other waste including litter and plastics*'. The EU Soil Strategy for 2030 [26] aims to prevent soil pollution and identifies chemicals, pesticides, fertilisers and pharmaceuticals as priorities for action. The Farm-to Fork Strategy, the EU Biodiversity Strategy for 2030 and the EU Soil Strategy for 2030 contain targets for the reduction of pesticide use. Of particular importance is the target to reduce the use of the most hazardous pesticides by 50% by 2030 as these pesticides have the potential to contain PMT/vPvM substances [27]. The Sustainable Blue Economy strategy highlights the importance of clean oceans and identifies chemical pesticides, nutrients and microplastic as main sources of pollution to be tackled [28]. The Circular Economy Action Plan addresses the presence of hazardous chemicals in products through the development of a sustainable policy framework intended to prevent and remove hazardous and persistent substances from contaminating secondary-raw-material-cycles [29]. The Circular Economy Action Plan largely picks up on the objectives of the Plastics Strategy, adopted in 2018, and before the Green Deal, to phase out substances that impede recycling processes. The Industrial Strategy sets the objective of creating green and digital transition pathways for 14 '*industrial ecosystems*', identified as priorities for the EU Recovery plan and investments projects. These 14 '*industrial ecosystems*' include sectors that are large users of chemicals, such as aerospace and defence, construction, transport and automotive, digital, electronics, energy intensive industries, renewable energies, mobility and textile. Green and digital transition pathways, which involve a co-creation process with stakeholders, should lead to specific voluntary pledges such as commitments on circularity and circular business models. The Sustainable Textile Strategy aims that by 2030 '*textile products placed on the EU market are [...] free of hazardous substances*' [30]. The Pharmaceutical Strategy aims to reduce the impact of pharmaceutical production and use on the environment, through the development of environmentally sustainable pharmaceuticals and the improvement of environmental risk assessment of chemicals, and to improve the disposal of medicines—in particular residues, that may have endocrine-disrupting potential or increase the risk of antimicrobial resistance.

Towards grouping and generic approaches to regulate PMT/vPvM substances

Key to preventative policy actions is the phase out and subsequent replacement of harmful PMT/vPvM substances with more labile, non-toxic substances. The CSS supports a gradual movement away from assessing and regulating chemicals substance-by-substance to regulating them in groups, be they based on structure or hazard [1]. The REACH Regulation [20] in Annex XI, Sect. 1.5 defines groups as REACH as substances that have "[a] common functional group; [b]common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in

structurally similar chemicals; or [c] a constant pattern in the changing of the potency of the properties across the category." Well-known examples of such groups are found in the Stockholm Convention of Persistent Organic Pollutants including chlorinated paraffins, polychlorobiphenyls, polybrominated diphenyl ethers. Currently, regarding persistent and mobile substances, the substance group receiving attention for their persistent and mobile properties are short-chain PFAS, as part of the PFAS Restriction Proposal [31].

The use of substance group approach to regulation will be supported by the implementation of the generic approach to risk management, which, according to the CSS, should become the default approach. The generic approach to risk management implies that risk management measures are automatically triggered based on the hazardous properties of a substance and generic exposure considerations. This approach is already implemented in several pieces of legislation for carcinogenic, mutagenic and reproductive toxicants (CMR), which are banned by default in consumer products such as cosmetics or toys. To support group assessments, the CSS plans that the generic approach will be extended to '*chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative*' [1]. However, this generic approach is not explicitly applied to PMT/vPvM substances, though this is still under consideration [32]. Before the generic approach to risk management is fully in place, the CSS plans for the prioritisation of substances falling under the generic approach for group restrictions. At the time of writing, a group restriction has been proposed on the manufacture, placing on the market and use of PFAS. This would cover around 10 000 substances and a public consultation has just been completed for this restriction. The conclusions of this restriction proposal are not likely to be fully implemented before 2025.

Gaps and opportunities in the policy framework

A critical need in implementing these strategies is the identification of legal gaps in the current policy framework to inform the development of the required enabling legislation. Gaps in a given legal framework are generally situations in which a desired (legal) state does not exist or in which objectives are difficult to realize, or not realised yet. In such situations, different actors identify different gaps or specific considerations. Such specific considerations can be, for example, environmental protection by preventing the entry of harmful substances into the environment, the generation of economic profits or the maximization of electoral votes. To fill in those gaps and take advantage of opportunities, measures are needed that achieve actor-specific objectives and bring about the desired state. Gaps and opportunities can be prioritized to further focus policy option development.

It is important to differentiate between source-directed measures, end-of-pipe approaches and general control strategies for chemical pollution [33]. The following can be applied: "*Source-directed solutions aim to reduce the entry of pollutants into water by encouraging producers to evade problematic substances and consumers to change their behaviour. End-of-pipe solutions aim at eliminating micropollutants from wastewater, mainly by improving the technology of wastewater treatment plants. Control approaches are preliminary strategies and include the monitoring of the level of pollution for further policy intervention*" [33]. Whilst there are many opportunities in the CSS, understanding the windows of these opportunities can be heightened by considering the theory of path dependence, as described in the political science literature [34, 35]. Path dependence represents an attempt to explain political decision-making processes by referring to state activity as an action that is always co-determined by a multitude of different contextual conditions, such as inter or transnational decision-making structures, actor constellations or even (de)globalisation tendencies, that often still follow established paths [35]. It is assumed that political decisions are heavily influenced by earlier decisions and political paths taken in the past are key in this regard. Due to this, regulation of chemicals via legally effective regulations like REACH make it difficult to switch to political alternatives due to self-reinforcing effects [34]. These self-reinforcing effects are a product of invested costs and efforts that went into the respective regulations. The development of REACH took many years for a viable concept, applicable to different stakeholder groups, to be implemented. Based on this, it is much more likely that REACH be expanded (albeit incrementally) rather than an entirely new approach to chemical regulation be developed. Thus, new approaches are expected to fit into and be integrated into REACH and existing legislation. Following the arguments of path dependence, real change often requires impactful situations (including crises)—so-called "*critical junctures*" [34]. They represent windows of opportunities, which open the possibility to change the course from the current political path. In this case policy change can occur, identified (legal) gaps can be addressed and new approaches can be incorporated into current activities. However, if this does not happen, the window of opportunity expires, and action continues on the chosen path [35]. A similar path dependent logic can be applied for the European chemicals policy as was observed for the introduction of the CSS. In this case, public and/or political awareness of shortcomings within chemicals policy at the time was the driver that ultimately resulted in the

CSS being introduced in 2022. On one hand, the CSS presents a timeline that implies a stable policy path, where current chemical regulations like REACH and CLP are further developed to steadily incorporate environmental protection standards, environmental principles (like the polluter pays principle) as well as up to date scientific and technical progress [36]. On the other hand, general increased environmental awareness and the introduction of the European Green Deal open up windows of opportunity for policy change. This also includes the regulation of PMT/vPvM substances [9, 33]. Opportunities for existing (legal) gaps are generated and by utilizing these emerging windows, policy change will occur. That being said, the implementation of the CSS will continuously depend on whether the window of opportunity to address the various aims remains open.

In relation to gaps and opportunities for PMT/vPvM substances, Bakker et al. previously identified four gaps related to the protection of human health and natural resources from exposure to accumulating very persistent (vP) substances [37]. These include (a) gaps in identifying and regulating vP substances, (b) gaps in regimes to protect the ecosphere from releases of vP substances, (c) deficits in controlling vP substances in the technosphere and (d) deficits in protecting human health and in addressing vP substance build-ups in the ecosphere [37]. Gaps exist in the context of product regulation and within the Circular Economy Action Plan in the context of a lack of life cycle assessment for persistent and very persistent substances in recycle streams given their lack of consideration and inclusion. In addition, there is a known gap related to the amount of substance property data available for many PMT/vPvM substances including PFAS [36, 37].

A further gap and opportunity may exist in the form of a lack of harmonization across European Chemicals Policy as has previously been documented for antimicrobial substances [38]. Kättström et al. showed that the same antimicrobial substance can be assessed and regulated in varying ways, depending on the use case. Currently, the Cosmetics Regulation and the Biocidal Products Regulation [39, 40] are not aligned, as the Cosmetics Regulation, for example, only requires an update on the properties of substances if the European Commission requests a re-evaluation of that substance, even in light of new scientific insights on health risks. However, the Biocides Regulation, would, for the same substance under a different use case, require that the competent authorities are informed independently as soon as new scientific insights on health risks are available that concerns the authorisation process. This requires that a manufacturer inform ECHA of this new information and then the Biocidal Product Committee, who are an expert ECHA committee, will work with this information and send it further to the European Commission [38]. Biocides and cosmetics are examples of products where PMT/vPvM substances can be found and it is reasonable to assume that corresponding gaps can be found when considering how several different pieces of legislation could be harmonized in the way that they address PMT/vPvM substances. Such gaps are relevant in the context of the One Substance, One Assessment legislative package that was adopted in December 2023. The Package aims to increase the efficiency and coherence of safety assessment of chemicals across legislation. To this end, a common data platform which is part of the One Substance, One Assessment legislative package will bring all information and data on chemicals from EU agencies and authorities in the same platform as well as creating a framework for monitoring chemical risks, measuring the effectiveness of chemicals legislation and measuring the transition towards the production of safe and sustainable chemicals.

Conclusion

The regulation of PMT/vPvM substances is in its infancy and it should be noted that regulation can also bring trade-offs upon implementation. However, of note is the impact assessment that was carried out by the European Commission prior to the introduction of the PBT/vPvB substances and PMT/vPvM substance hazard classes, concluding that the "Preferred option" was to introduce these classes. Within this analysis, costs of introducing these classifications, and consequent withdrawal of these substances from the market were calculated to be between 0.2 and 0.7 €/kg of PBT/vPvB and PMT/vPvM substances. However, this was easily offset in the case of PMT/vPvM substances by the cost of their removal from the environment alone, with the example of perfluorooctyl sulfonate (PFOS), being 35 000 €/kg. This figure does not take into consideration health costs which would only increase this cost [41].While many EU action plans exhibit gaps and opportunities for chemical regulation as a whole, only certain policies refer to PMT/vPvM substances directly. The introduction of new hazard classes in the CLP regulation for these substances provides an important starting point that creates new windows of opportunity for better inclusion of these substances in European Chemicals Policy in the future. This is enhanced by the indirect reference to PMT/vPvM substances in many of the current ambitions of the European Union.

This opens the pathway to close gaps and address opportunities in other realms of European Chemical Policy to enable the Chemicals Strategy for Sustainability. Critical to this is how newly identified hazard class of PMT/vPvM substances is utilized in revisions

to regulations such as REACH (i.e. inclusion of PMT/vPvM substances as SVHCs in Article 57 of REACH, as announced in the CSS) or to regulations already containing exclusion criteria based on hazard classes (currently mainly CMRs), such as the Biocidal Product Regulation, Plant Protection Product Regulation, or other risk management measures based on hazard classes, such as the Industrial Emissions Directive. Current revisions of legislation may also provide opportunities. In its proposal for a Directive on the Union code relating to medicinal products for human use, the Commission proposed to subject to medical prescription medicinal products containing active substances classified as PMT and vPvM substances [42]. In its amendments to the Commission proposal for the revision of the water legislation [43], the European Parliament included PMT and vPvM substances to the definition of 'priority hazardous substances' in the Water Framework Directive, which would require Member States to take the necessary measures in their river basin management plans to 'cease or phase out emissions, discharges and losses' of these substances to water [44]. Currently, these changes are at the proposal stage and it remains to be seen if they will be adopted in the final text.

Linking European regulations with international regulations regarding PMT/vPvM substances is a necessary step for realisation of the CSS [10, 37], due to the vast amount of trade in chemicals between EU in the rest of the world. The global dimension of chemicals regulation presents a complicating factor as environmental problems are not usually restricted by national borders. The EU is coordinating an informal working group to support the introduction of hazard classes related to persistence and mobility in the United Nations Global Harmonized System (UN-GHS) [45]. If this were to be carried through and implemented, it would allow gaps and opportunities to be addressed on a global scale to protect the environment and human health from persistent and mobile substances [46]. It is up to policymakers, regulators and academia to highlight those gaps and emerging windows of opportunity that reflect potential regulatory engagement.

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All authors contributed to drafting, writing and revising the manuscript, as well as approving the submitted version and are accountable for their own contributions and accuracy.

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