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D5.3 - Policy brief on PM(T) concerns and actions in EU

DEVELOPING EFFECTIVE STRATEGIES TO TACKLE PERSISTENT, MOBILE AND TOXIC SUBSTANCES IN THE SOIL-SEDIMENT-WATER SYSTEM: TOOLS AND BOUNDARY CONDITIONS FROM THE HORIZON 2020 PROJECT PROMISCES

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Executive Summary

Persistent, mobile, and potentially toxic (PM(T)) substances in the soil-sediment-water system prevent both the reuse of natural resources and the realization of a safe circular economy in Europe, which is one of the objectives of the European Green Deal. Regulations related to the soil-sediment-water system, e.g. the Water Framework Directive (2000/60/EC), and its daughter directives, the Groundwater Directive (2006/118/EC), and the Priority Substances Directive (2013/39/EU), the Drinking Water Directive (EU/2020/2184 revision from 98/83/EC), the Urban Waste Water Treatment Directive (2022/0345(COD), revision of 91/271/2024), as well as regulations focusing on the introduction of chemicals, e.g. REACH (2006/1907/EC), Biocidal Products Regulation (528/2012/EC), and Pesticides regulations (EC 1107/2009 and 2009/128/EC), do not offer sufficient provisions to address these chemicals effectively in a circular economy and sustainable use of natural resources. Regulations related to industrial emissions like the Industrial Emissions Directive (2010/75/EC) and the European Pollutant Release and Transfer Register (E-PRTR, 2000), the Integrated Pollution Prevention and Control (IPPC) Directive (96/61/EC, Article 15) also lack sufficient provisions to effectively manage emissions of these substances.

This policy brief describes the most urgent areas of concern when it comes to PM(T) substances in Europe and identified policy gaps. It presents the results from extensive data analysis on sectors of most concern due to use of PM(T) substances, stakeholder co-creation workshops on barriers and solutions, and it presents the first sketches of a Decision Support Framework (DSF) that facilitates implementation of Zero Pollution and Circular Economy Action plans. Recommendations on how to improve current treatment approaches and potential innovations to tackle PM(T) substances in the Circular Economy will be included in PROMISCES deliverable D5.8 dedicated to policy recommendations (February 2025).

PM(T) substances, including degradation products, are persistent in the environment, highly soluble in water, and are therefore easily transported through the environment. Furthermore, because of their physicochemical properties, PM(T) substances are poorly removed in conventional treatment processes, making them a risk to safe drinking water supplies and food production in Europe.

The analysis so far, brings forward several conclusions and recommendations relevant to policymakers at European and national levels. To achieve Zero Pollution and Circularity, the following policy actions are needed:

- The development of adequate strategies for enabling circular economy routes that involve PM(T) substances strongly relies on the *availability of accurate data* on substance intrinsic properties, as well as the quantities and types of use. With those data available, it is feasible to prioritize PM(T) compounds regarding hazards and risks on a per-compound and a (preferably) per-use basis and thus provide input to policy makers and other actors for developing adequate strategies.
- In the current registration procedures under REACH and other regulatory frameworks, however, the lack of detailed and accurate information on uses, especially downstream uses, obscures the identification of sectors of most concern regarding use of PM(T) substances. In addition, confidential business information and the lack of data requirements for substances used as intermediates make this even more difficult. To achieve a comprehensive assessment of the impact of PM(T) substances throughout their lifecycle, it is essential to *expand quantitative exposure data requirements*, such as tonnage bands, beyond the scope of REACH

regulation. This extension should encompass other regulatory domains, including pharmaceuticals, biocides, cosmetics, in accordance to the One Substance-One Assessment (OSOA) approach as recently proposed by the European Commission.

- Policy development in a circular economy at European, national and regional levels and even beyond Europe (i.e. import/export regulation) should hold the prevention of PM(T) substances in the environment as the basic design principle, *e.g.*, following the *Safe and Sustainable by Design* principle, as this is the most effective type of solution. To support this principle, PROMISCES is developing tools to help identify critical substances and compare them to potential alternatives for substitution.
- Although geographical and cultural conditions are important, local stakeholders stress the need for tangible objectives and boundary conditions, at both the European and national levels, to effectively address the problems associated with PM(T) substances. In addition, local and regional authorities need to communicate and interact with all stakeholders and authorities involved in the circular economy route and its context to find the optimal (combination of) solutions.

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1 Introduction

1.1 Background

Persistent, mobile, and potentially toxic (PM(T)) substances in the soil-sediment-water system prevent both the reuse of natural resources and the realization of a safe circular economy in Europe, which is one of the objectives of the European Green Deal. Regulations related to the soil-sediment-water system, e.g. the Water Framework Directive (2000/60/EC), and its daughter directives, the Groundwater Directive (2006/118/EC), and the Priority Substances Directive (2013/39/EU), the Drinking Water Directive (EU/2020/2184 revision from 98/83/EC), the Urban Waste Water Treatment Directive (2022/0345(COD), revision of 91/271/2024), as well as regulations focusing on the introduction of chemicals, e.g. REACH (2006/1907/EC), Biocidal Products Regulation (528/2012/EC), and Pesticides regulations (EC 1107/2009 and 2009/128/EC), do not offer sufficient provisions to address these chemicals effectively in a circular economy and sustainable use of natural resources. Regulations related to industrial emissions like the Industrial Emissions Directive (2010/75/EC) and the European Pollutant Release and Transfer Register (E-PRTR, 2000), the Integrated Pollution Prevention and Control (IPPC) Directive (96/61/EC, Article 15) also lack sufficient provisions to effectively manage emissions of these substances.

PM(T) substances, or their degradation products, are persistent in the environment, highly soluble in water, and are therefore easily transported through the environment. Furthermore, because of their physicochemical properties, PM(T) substances are poorly removed in conventional treatment processes, making them a risk to safe drinking water supplies and food production in Europe.

As described by the European Commission[1], pollution by PM(T) substances is often a systemic problem. It is related to the ways of production, use, and emission of these chemicals and is aggravated by missing technical solutions and monitoring techniques in the soil-sediment-water system. PM(T) substances also pose challenges for regulatory authorities to develop or enforce effective policies throughout their lifecycle. Solutions for PM(T) substances should be environmentally sustainable, cost-effective, easily implementable, and suitable for real-life challenges. Such solutions need to be employed for substances for which the more basic preventive approach of *Safe and Sustainable by Design* (SSbD) – one of the core preventive principles of the Chemical Strategy for Sustainability – does not (yet) apply. To meet these requirements, close consultation or collaboration with potential end-users to generate, evaluate, and implement potential solutions is needed. The Horizon 2020 project PROMISCES aims to deliver solutions to overcome the challenge of PM(T) substances in the soil-sediment-water system and support the ambitions set in the Green Deal and related regulations (Promisces | Home). PROMISCES runs from November 2021 to April 2025.

[1] *https://cordis.europa.eu/programme/id/H2020_LC-GD-8-1-2020/en*

1.2 Structure and objective of this policy brief

This policy brief identifies policy gaps regarding PM(T) substances in Europe and presents highlights, key findings, and recommendations to help policymakers take adequate actions. It delivers the results from extensive data analysis on sectors of most concern due to their use of PM(T) substances, stakeholder co-creation workshops on barriers and solutions, and it presents the first sketches of a Decision Support Framework (DSF) that facilitates the implementation of Zero Pollution and Circular Economy Action plans.

2 Highlights

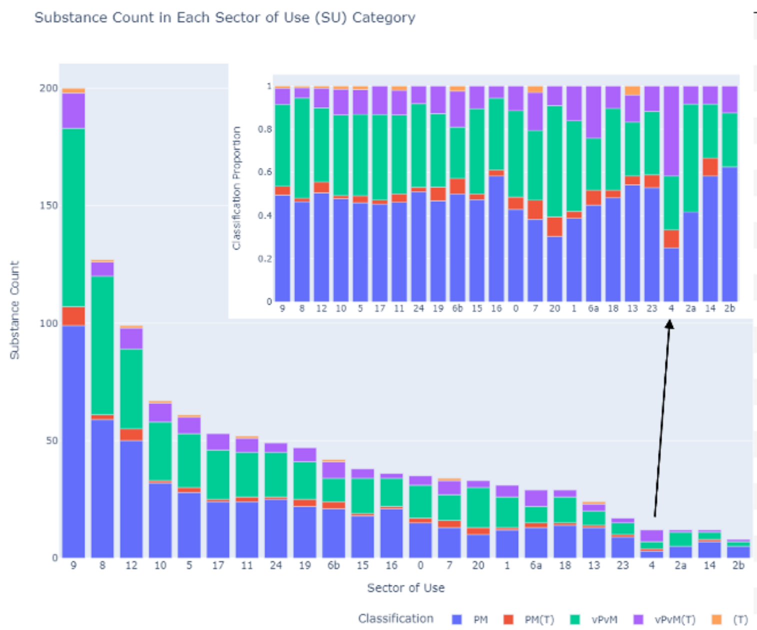
- The PROMISCES project has identified sectors of concern for persistent, mobile, and toxic (PM(T)) substances. Confidentiality and the registration of substances as intermediates in registration procedures under REACH, however, may obscure the identification of areas of concern and adequate strategies for enabling circular economy routes in the frame of the ambitions set in the Green Deal and related regulations.
- A Decision Support Framework (DSF) is being developed by PROMISCES to identify the most effective strategies to reduce risks from PM(T) substances in the soil-sediment-water system. Stakeholder interactions bring forward the importance of creating governance structures and financial support, including social perspectives when developing viable strategies for minimizing and preventing PM(T) pollution.
- One of the data products of the DSF will be a mapping tool to identify sectors of use and product categories where substitution of PM(T) substances by less harmful alternatives should be considered a priority to reduce risks. Preventing pollution by substituting PM(T) substances is the most effective way of addressing potential issues with these substances in the circular economy.

3 Key findings

3.1 Mapping PM(T) substances across sectors of use in the EU to prioritize urgent actions

The categorisation of ~500 potential PM(T) substances by their sectors of use (SU), as defined by REACH, shows a widespread use of PM(T) across sectors (Figure 1).

Over half to two-thirds of the substances mapped as PM(T) compounds by the PROMISCES project are used in the chemical production sector, *i.e.* early in the supply chain. These are thus likely to affect all further economic activities via products containing them. This observation comes from a systematic mapping study in which substances that are potentially grouped under the PM(T) label were classified for different sectors of use, combining different data sources and scenarios for classification (Figure 1). As an example, the manufacture of Food products (SU 4), which is highly relevant for human health, has the largest proportion of vPvM(T) substances, a group characterized by (very) high persistency, mobility, and toxicity scores. This result identifies SU 4 as a sector for priority attention and potential remedial action. There are 12 substances in this group, that in total have a rough tonnage production of 125,000 tons per year and can be found in dishes, pots/pans, food storage containers and food packaging.



Sector of Use	Description
SU 0	Other
SU 1	Agriculture, forestry and fishing
SU 2a	Mining (without offshore industries)
SU 2b	Offshore industries
SU 4	Mfg. of food products
SU 5	Mfg. of textiles, leather, fur
SU 6a	Mfg. of wood and wood products
SU 6b	Mfg. of pulp, paper and paper products
SU 7	Printing and reproduction of recorded media
SU 8	Mfg. of bulk, large scale chemicals (including petroleum products)
SU 9	Mfg. of fine chemicals
SU 10	Formulation [mixing] of preparations and/or re-packaging (excluding alloys)
SU 11	Mfg. of rubber products
SU 12	Mfg. of plastics products, including compounding and conversion
SU 13	Mfg. of other non-metallic mineral products, e.g. plasters, cement
SU 14	Mfg. of basic metals, including alloys
SU 15	Mfg. of fabricated metal products, except machinery and equipment
SU 16	Mfg. of computer, electronic and optical products, electrical equipment
SU 17	General manufacturing
SU 18	Mfg. of furniture
SU 19	Building and construction work
SU 20	Health services
SU 23	Electricity, steam, gas water supply and sewage treatment
SU 24	Scientific research and development

Figure 1. Number of substances and their mapping classification for ECHA's Sectors of Use (SU).
On top, the proportion of each classification per sector of use is displayed.
Legend: PM: persistent and mobile; vPvM: very persistent and very mobile;
vPvM(T): very persistent, very mobile and toxic; Mfg.: Manufacture.

Based on the results obtained with this type of mapping, it is concluded that this methodology improves the possibilities for identification and categorization of new PM(T)'s and thus for prioritization of potential actions that prevent and limit their emission to the environment and associated risks. Although not shown in Figure 1, the data analyses also focus on chemical identity, tonnage, and PM(T) characteristics, thus yielding an optimal mapping and prioritization approach per substance (Sardi et al., 2024).

Mapping and prioritization of areas of concern is hindered by the lack of detailed information on exposure through the substance's lifecycle.

The mapping so far, provides insights on hazards of PM(T)s used in the ECHA's sectors of use. However, the net level of risks caused by PM(T)s also depends on exposure. This information is of key interest for prioritization of (policy) actions. The level of exposure is estimated on three indicators: tonnage, release during use, and the range of use, *e.g.*, wide dispersive use. By combining exposure levels with hazard information, it becomes possible to map and prioritize areas of concern that would benefit the most from risk reduction measures on PM(T) compounds.

Exposure insights are, however, complex to obtain. For example, a high number of substances are listed as intermediates (product category 19[2]; n=153), 38% of which have a double REACH registration (full and intermediate substance registration). This status indicates a wide application of these substances in many economic sectors. However, tracing their impact is not possible as REACH intermediate registration dossiers do not require tonnage and use specifications. For instance, for a substance known to be used in manufacturing coatings, adhesives, and composite materials, providing enhanced mechanical properties and improved heat resistance, the tonnage data for the complete registration (both full and intermediate) has been flagged as confidential, which prevents proceeding from the hazard to the risk stage. Consequently, a risk-based management approach for PM(T) substances in the soil-sediment-water system cannot be developed.

In general, information on uses suffers from imprecision at the source, primarily due to data aggregation in the compound dossiers (*e.g.*, tonnage band of substances presented as total per substance and not per use), hindering traceability and precise identification of the uses in the value chain. The lack of sufficiently specific data on uses and associated emissions results in insufficient information for identifying relevant solutions for risk reduction for human health and the environment along value chains, underlining the importance of identifying intrinsic PMT/vPvM properties early on and applying the new hazard classes added for PMT and vPvM to the CLP (Classification, Labelling, and Packaging) Regulation (EC/1272/2008).

The Chemical Strategy for Sustainability envisions the CLP as the central piece of chemical regulation, moving from a generic approach to risk management and One Substance-One Assessment (OSOA) approach. In particular, certain substances may be used in articles, such as polymers or additives in food contact materials, and generate solid waste. As an example, the combined classification as PMT/vPvM substance and as a Substance of Very High Concern (SVHC) according to REACH (2006/1907/EC, Article 57) triggers the obligation (2006/1907/EC, Article 33) to declare the presence of SVHC in the supply chain if their weight in the article is higher than 0,1%. Likewise, provisions from Article 20 in the Waste Framework Directive (2008/98/EC) lead to the declaration in the SCIP database (operated by ECHA) of all articles containing more than 0,1% by weight of SVHC. Implementing CLP Regulation alone would not fill data gaps on uses down the supply chain for intermediate substances. However, the labelling as PM(T)/SVHC will improve the waste management of articles containing PM(T) substances and inform the industrial sector of their associated risk.

[2] *https://echa.europa.eu/documents/10162/17224/information_requirements_r12_en.pdf*

The result observed in the context of REACH dossiers of PM(T) substances will likely be confirmed or even accentuated for uses linked to other regulations (pharmaceuticals and biocides), due to the even larger scarcity of quantitative data on uses and tonnage bands per use.

Due to missing information, exposure to PM(T) compounds can be falsely considered to be low, which may result in the substance disappearing from the priority list of areas of concern during the mapping. The mapping of hazards and risks can only be improved if this information gap, resulting from both regulatory and disclosure gaps, is addressed at the European level.

3.2 Tackling PM(T) substances: Need for solutions at different levels

Technical solutions for PM(T) substances are being developed

PM(T) substances are only limitedly represented in regular monitoring schemes that are executed in the context of the Water Framework Directive, the Drinking Water Directive and the Groundwater Directive (e.g. Watch Lists for surface water and groundwater). Furthermore, they are difficult to remove with existing treatment techniques. In PROMISCES, new technologies are being developed that support the prevention, identification, risk assessment, and removal by treatment of PM(T) substances in a circular economy. The solutions found in PROMISCES will be made available to stakeholders in a Decision Support Framework (DSF) to help identify the most effective solutions for their needs. Furthermore, specific recommendations on how to improve current treatment approaches and potential innovations to tackle PM(T) substances in the Circular Economy will be included in a PROMISCES deliverable dedicated to policy recommendations. This report is due February 2025.

The decision support framework is based on the principles of the toxic-free hierarchy and adapted to PM(T) substances by Hale et al. (2022) (see also Figure 2). Whenever possible, PM(T) substances should be prevented from entering the soil-sediment-water system, preferably by reducing their use through substitution with less problematic substances. This is more effective than trying to control risks or remediate the environment, as due to their mobile and persistent properties these compounds are hard to identify and remove. Not reducing the use of PM(T) substances may risk generating large quantities of PM(T) hazardous waste, with the potential of introducing pollution in other places.

Even though prevention is preferable, it is not always possible and solutions for the identification, treatment and risk assessment of PM(T) substances in the soil-sediment-water system are still required, especially in light of the PM(T) substances currently being used and already present in the environment. The "Solutions" module of the DSF that is being developed within PROMISCES will therefore consist of four different blocks, that address all these aspects (Figure 3).

These are solutions to:

1. *prevent* PM(T) substances from entering the soil-sediment water system (e.g. by reducing their use through substitution with less hazardous substances);
2. *identify* the pollution (e.g. analytical techniques);
3. *assess* the *risk* of a given resource (e.g. bioassays); and
4. *treat* polluted sources- (e.g. advanced treatment techniques of water, landfill leachate, soil and groundwater)

The Decision Support Framework, including examples of the assessment of available solutions for several PM(T) substances, will be made publicly available in early 2025.

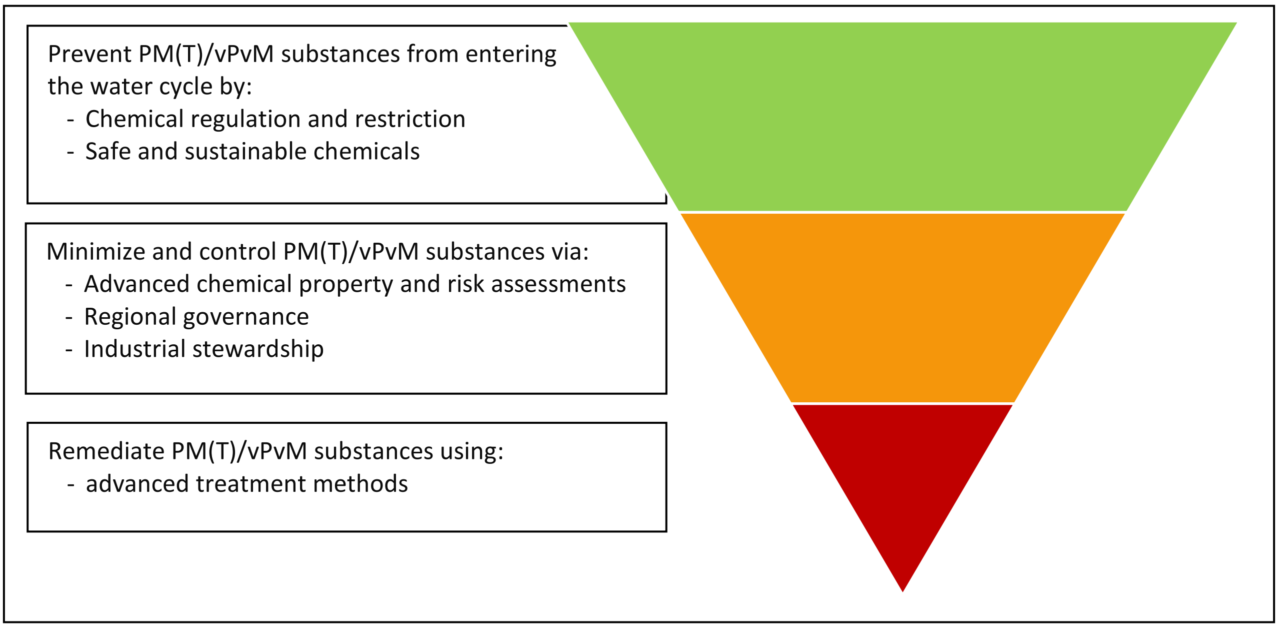


Figure 2. Ways of addressing PM(T) substances and their place in the toxic-free hierarchy (Hale et al.,2022).

Importance of stakeholder views on PM(T) solutions in the Circular Economy

The solutions developed within PROMISCES are technological in essence. However, the availability of technical solutions by themselves is not sufficient to successfully address PM(T) substances in the soil-sediment-water system. Social, economic, and governance conditions can impact the successful implementation of solutions towards a safe and sustainable circular economy. Examples of these conditions can include clarity on standards that need to be met, the division of roles and responsibilities and the availability of financial means. Therefore, creating a viable implementation strategy requires a systemic view on the problem(s), potential solutions, and their boundary conditions.

The role of the boundary conditions for the implementation of strategies to deal with PM(T)s within a circular economy route is being studied in the PROMISCES project via co-creation workshops for different circular economy routes with local stakeholders (Figure 3).

So far, the results from the first local stakeholder workshop have been analysed. These results highlight the importance of the economic, social and governance boundary conditions that must be met to address problems along the circular economy route, thereby enabling the implementation of technical solutions. To exemplify this, stakeholders identified several boundary conditions that they see as supportive, to be incorporated in the technical solutions for prevention, treatment, etc. to further the implementation of these solutions. Examples of these identified conditions include defining funding mechanisms for additional treatment steps, improving public acceptance of the reuse route via targeted dissemination, establishing round tables of experts and actors across sectors to share responsibility, and establishing limit levels for substances in legislation.

Figure 3. Systemic view of the types of solutions in the DSF. Solutions related to prevention, monitoring, risk assessment and treatment are interconnected in multiple ways. Boundary conditions such as governance, financial support, or social perspectives are important to consider in coherence with other types of solutions within the circular economy route.

4 Policy Recommendations

To achieve Zero Pollution and Circularity, the following policy actions are needed:

- The development of adequate strategies for enabling circular economy routes involving PM(T) substances strongly relies on the *availability of accurate data* on substance characteristics, tonnage, and type of use. With those data available, it is feasible to prioritize PM(T) compounds regarding hazards and risks on a per-compound and a (preferably) per-use basis and thus provide input to policy makers and other actors for developing adequate risk assessment and prioritization strategies.

- In the current registration procedures under REACH and other regulatory frameworks like the Biocidal Products Regulation (528/2012/EC), and Pesticides Directive (2009/128/EC) however, the lack of detailed and accurate information on uses, especially downstream uses as well as confidentiality and the registration of substances as intermediates, obscures the identification of sectors of most concern regarding their use of PM(T) substances.

- To achieve a comprehensive assessment of the impact of PM(T) substances throughout their lifecycle, it is essential to *expand quantitative exposure data requirements*, such as tonnage bands, beyond the scope of the REACH regulation. This extension should encompass other regulatory domains, including pharmaceuticals, biocides, cosmetics, in accordance to the One Substance-One Assessment (OSOA) approach as recently proposed by the European Commission.

- Identifying substances with intrinsic PMT/vPvM properties and implementing the related CLP Regulation is essential to protect human health and the environment. Furthermore, it will be necessary to amend the nearly 20 EU regulations that rely on one or more CLP criteria, to incorporate the new hazard classes related to PMT/vPvM properties.

- PM(T) should be included as Safe and Sustainable by Design (SSbD) criteria and communicated to stakeholders, including through sectorial regulations. Policy development in a circular economy at the European, national, and regional levels should include the prevention of PM(T) substances in the environment as the basic design principle, as this is the most effective type of solution. To support this principle, PROMISCES is developing and applying tools, such as the PMT-assessment tool, to help identify PM(T) substances and compare them to potential alternatives for substitution.

- Local stakeholders stress the need for tangible objectives and clear policies from the EU or from national governments on PM(T) substances. In addition, strong local partnerships with all stakeholders and authorities involved in the circular economy route and its context are needed to find the optimal (combination of) solutions.

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