




Zero PM

Zero pollution of Persistent, Mobile substances

Grant Agreement No. 101036756



Update on EU policy initiatives contributing to the prevention, prioritisation and removal of persistent and mobile substances in 2024

Work Package 3 – Policy analysis, development, and assessment

January 2025

Initiatives adopted in 2024

EPR system and PFAS monitoring in recast Directive on Urban Wastewater Treatment

Directive (EU) 2024/3019 on urban wastewater treatment was published in the Official Journal in December 2024 and entered into force on 1 January 2025. The Directive introduced stricter requirements in terms of water treatment: by 2039 and 2045 respectively, Member states will have to ensure the application of tertiary and quaternary treatment in larger plants of 150 000 population equivalent (p.e.) and above, and for smaller agglomerations of 10 000 p.e. and above by 2045 (with progressive deadlines).

The new Directive introduced an extended producer responsibility scheme in which producers of pharmaceuticals and cosmetics will contribute a minimum of 80% of the costs of quaternary treatment to remove micropollutants resulting from the products they place on the market. Producers are exonerated from EPR if the quantity of the substances contained in the products they place on the EU market is below 1 tonne per year or if the substance in products they place on the market are rapidly biodegradable in wastewaters or do not generate micro-pollutants in wastewaters at the end of their life. Member States have until 31 December 2028 to establish their national system to implement the extended producer responsibility scheme.

The Directive set new monitoring requirements for agglomerations of above 10 000 p.e., where Member States must monitor at the inlets and outlets of urban wastewater treatment plants, the concentration and loads in the urban wastewater of pollutants listed

in the Water Framework Directive, the Environmental Quality Standards Directive, the Groundwater Directive, the Industrial Emissions Portal, the Sewage sludge Directive, parameters listed in Drinking water directive when waste water is discharged in a catchment area (for PFAS, Member states can choose to use one or both parameters 'PFAS Total' and/or 'Sum of PFAS'), and listed in the Bathing Water Directive when waste water is discharged into bathing water areas during bathing seasons and the presence of microplastics. Regarding PFAS monitoring, the Directive tasked the Commission to establish a methodology for measuring 'PFAS Total' and 'Sum of PFAS' in urban wastewater by July 2027. The Directives set the monitoring frequencies at: at least two samples per year, with maximum 6 months between the samples, for agglomerations of 150 000 p.e. and more; at least one sample every two years for agglomerations of between 10 000 p.e. and 150 000 p.e.

Based on the monitoring data obtained on PFAS and microplastics in wastewater, the Commission is requested to evaluate, by 31 December 2033, the feasibility and relevance of developing an Extended Producer Responsibility system for products generating PFAS and microplastics.

Restriction on Food Contact Packaging containing PFAS in recast Packaging and Packaging Waste Regulation

The recast [Regulation on Packaging and Packaging Waste](#) was formally adopted in December 2024 (not yet published in the Official Journal). The Regulation introduced a restriction on the placing on the market of food contact packaging containing PFAS. This restriction was initially proposed by the European Parliament during the legislative process, and raised intensive debates across institutions, linked to likely overlaps with the PFAS restriction under REACH, currently under development, which should apply to food contact material and packaging for consumer articles.

The Regulation (Article 5(5)) prohibits, starting 18 months after the entry into force of the Regulation, the placing on the market of food-contact packaging containing PFAS in concentrations equal to or above:

- ▼ 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFAS excluded from quantification);
- ▼ 250 ppb for the sum of PFAS measured as the sum of targeted PFAS analysis, where applicable with prior degradation of precursors (polymeric PFAS excluded from quantification); and
- ▼ 50 ppm for PFASs (including polymeric PFAS).

The Regulation adopted the same definition of PFAS as the one used in the PFAS restriction under REACH, currently under review.

To avoid possible overlaps with the REACH restriction, the Regulation tasked the Commission to assess, five and a half years after the entry into force of the Regulation, the need to amend or repeal Article 5(5) of the Packaging and Packaging Waste Regulation.



Publication of the Commission Communication on the Essential Use Concept

Announced in the Chemical Strategy for Sustainability in 2020, the Communication defining ‘[guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals](#)’ was published by the Commission on 22 April 2024. The communication defined that ‘the use of a most harmful substance is essential for society if that use is necessary for health or safety or is critical for the functioning of society and there are no acceptable alternatives’. These might cover critical uses in a wide range of sectors such as healthcare, energy, transport, water and waste treatment, digital communication, defence, disaster management, environmental protection, scientific research or cultural heritage protection. The definition applies to substances that are CMR 1A or 1B, endocrine disruptors for human health and the environment (category 1), respiratory sensitisers (category 1), toxic to specific organs after repeated exposure (category 1), PBT/vPvB, hazardous to the ozone layer (category 1), and subject to further assessment to PMT/vPvM. The essential use concept will however only have legal effect when introduced into specific legislation. The Communication did not specify in which legislation the concept will be or should be introduced or how this assessment will be integrated into decision-making.

Update of CLP guidance with information on new hazard classes, including PMT/vPvM

To accompany the implementation of the new hazard classes, ECHA has updated the [guidance on the application of the CLP Regulation criteria](#). The guidance gathers available reliable information to conclude on each property (e.g. P, vP, M, vM), information on the application of a weight of evidence to conclude on classification and labelling, provisions on dealing with multiple studies for the same property, and information on mixture classification. The guidance contains specific considerations on pesticides and biocides (such as additional test methods or approaches), and other issues like outliers, treatment of values very close to regulatory thresholds, use of (Q)SARs, monitoring data or modelling. The guidance also includes updated information on rulings of the European Court of Justice.

Main ongoing initiatives to follow in 2025

Legislative procedures

Chemicals industry package and revision of the REACH Regulation

The Commission announced for 2025 a chemicals industry package, which will include a legislative proposal for the revision of the REACH Regulation. The European Commissioner for Environment [indicated](#) that the revision will ‘simplify and modernise the regulatory framework’, ‘review the dual system of authorisations and restrictions, in order to substantially reduce the need for individual authorisations of uses of hazardous substances’ and ‘improve information requirements in key areas such as endocrine disruptor’.



Revision of the water legislation

The Commission published in October 2022 a proposal revising the Water Framework Directive, the Groundwater Directive and the Environmental Quality Standards Directive in order to update the lists of water pollutants to be more strictly controlled in surface waters and groundwater. The Parliament adopted its position in September 2023 and the Council on 19 June 2024. Interinstitutional negotiations will be held and might be concluded during the Polish Presidency (January-June 2025).

Revision of the EU general pharmaceuticals legislation

The Commission published a proposal revising the EU pharmaceuticals legislation in April 2024. The revision contains a proposal for a new Directive on the Union code relating to medicinal products for human use and a new Regulation on Union procedures for the authorisation and supervision of medicinal products for human use. Work on the proposed text is ongoing in both institutions. The European Parliament adopted its position in April 2024. Work in the Council will continue during the Polish Presidency (January-June 2025).

Soil Monitoring and Resilience Directive

The Commission published the proposal for a Soil Monitoring and Resilience Directive in July 2023, which contains provisions on the identification and remediation of contaminated sites. The European Parliament adopted its position in April 2024 and the Council in June 2024. Interinstitutional negotiations started in October 2024 but no agreement was reached by the end of the year.

‘One Substance, One Assessment’ legislative package

The Commission adopted on 7 December 2023 the ‘One substance, one assessment’ legislative Package. The Package includes three legislative proposals deriving from the ‘one substance, one assessment’ initiative, announced in the Chemicals Strategy for Sustainability, aiming to increase the efficiency and coherence of safety assessment of chemicals across legislation. The Package contained a proposal for a Regulation establishing a common data platform on chemicals and a proposal for a Regulation and Directive amending several existing legal acts with the aim of streamlining risk assessment tasks and improving cooperation across EU agencies. The Council has adopted its mandates for negotiations in June 2024. Work is still ongoing in the European Parliament, adoption in plenary is expected in March 2025.

Toy Safety Regulation

The proposed Regulation extends the generic restrictions (which were already existing for CMRs) to other groups of substances including endocrine disruptors, substances toxic for a specific organ and respiratory sensitizers. The European Parliament adopted its position in March 2024 in which it proposed to extend the list of generic prohibitions to SVHCs, PBT, vPvB, PMT, vPvM, and skin sensitizers category 1 and to prohibit the use of PFAS and bisphenols in toys, components of toys or micro-structurally distinct parts of toys. The Council adopted its mandate in May 2024, and only marginally



extended the list of prohibited substances, including skin sensitizers category 1A. Interinstitutional negotiations started in November 2024 and are ongoing.

Delegated and implementing acts

General PFAS restriction

The REACH restriction proposal aiming to restrict PFAS as a group, drafted by the national authorities of Denmark, Germany, the Netherlands, Norway and Sweden, was published by ECHA on 7 February 2023. A public consultation on the restriction proposal was held between 22 March 2023 and 25 September 2023. ECHA received more than 5 600 comments from more than 4 400 organisations, companies and individuals. Opinions of RAC and SEAC are under development.

In November 2024, ECHA and national authorities have published a [progress update](#). The Risk Assessment Committee (RAC) has reached a provisional conclusion on the hazard assessment of PFAS. Given the wide scope of the restriction, the RAC and the Socio-Economic Analysis Committee (SEAC) have taken a sector-based approach to assess the risks and socio-economic impacts of the restriction. The two committees have so far reached provisional conclusions on five sectors: consumer mixtures and miscellaneous consumer articles, cosmetics, ski wax, metal plating and manufacture of metal products and petroleum and mining. Discussions on at least six more sectors are [planned in 2025](#) and new uses have been identified based on consultation inputs (sealing applications, technical textiles, printing applications and other medical applications, such as packaging and excipients for pharmaceuticals).

According to the progress note, following the consultation, Committees are considering whether restriction options other than a ban could achieve the aim to significantly reduce the PFAS emissions throughout their life cycle, in particular for sectors where the socio-economic impacts may be disproportionate. Such options could be setting conditions for the continued manufacture, placing on the market and uses of PFAS until suitable alternatives are available. Sectors where such options are considered are batteries, fuel cells, and electrolyzers, and they could be considered for other sectors, such as medical devices, semiconductors and fluoropolymers.

Restriction of PFAS in firefighting foams

The proposed restriction, published in 2022, would ban the placing on the market, use and formulation of all PFAS in firefighting foams after use or sector-specific transition periods. The RAC adopted its opinion in March 2023 and the SEAC in June 2023; both Committees support the option proposed in the restriction dossier. The restriction has not yet been adopted.

First harmonised classifications for PMT/vPvM hazard classes: TFA

Germany has submitted two dossiers for revising the harmonised classification of trifluoroacetic acid (TFA) and adopt a new harmonised classification for sodium trifluoroacetate and other inorganic salts of trifluoroacetic acid in June 2024. New



proposed hazards include PMT, vPvM and Reprotoxic 1B. ECHA is currently running the accordance check on both dossiers.

Ban of pesticide active substance degrading into TFA

The Commission proposed in November 2024 the non-renewal of the approval of active substance flufenacet under the Plant Protection Product Regulation. In its [scientific opinion](#) published in September 2024, EFSA concluded that the active substance meets the criteria to be identified as an endocrine disruptor and identified very high potential for groundwater contamination by trifluoroacetic acid (TFA). The regulation not renewing the approval of the substance could be adopted in the first half of 2025.

First ESPR working plan

The Ecodesign for Sustainable Product Regulation (ESPR) was published on 28 June 2024 and entered into force on 18 July 2024. The Regulation will be progressively implemented through the adoption of delegated acts for specific product groups. In March 2025, the Commission is expected to adopt the first ESPR working plan, setting out which products will be prioritised over the coming years. Chemicals, but also paint, detergents, or lubricants, are listed in the ESPR among the products that must be prioritised in the first working plan (unless duly justified).

Communications and strategies

Commission Roadmap to phase out animal testing in chemical safety assessments

The European Commission is preparing a roadmap that ‘outline milestones and specific actions (legislative and non-legislative) to be implemented in the short to longer term to further reduce and ultimately phase out animal testing under all relevant pieces of chemical legislation (e.g. REACH, Biocidal Product Regulation, Plant Protection Products Regulation and human and veterinary medicines)’. The roadmap should in particular set out a ‘path to expanding and accelerating the development, validation and implementation of non-animal methods as well as means to facilitate their uptake across legislation’. A call for evidence was held in 2024 and stakeholders’ workshops have been organised. The Roadmap is expected to be released in 2025.

European Water Resilience Strategy

The Commission has [announced](#) the development of a European Water Resilience Strategy addressing ‘water efficiency, scarcity, pollution and water related risk’ as a priority of the upcoming Commission term. The timeline of the initiative is still uncertain.





H2020 project Zero pollution of Persistent, Mobile substances
EU Grant Agreement No. 101036756