



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 2023

Work Package 3 – Policy analysis, development, and assessment

January 2024

Initiatives adopted in 2023

Introduction of PMT / vPvM hazard classes

As announced in Chemicals Strategy for Sustainability (CSS), two new hazard classes for PMT and vPvM substances have been introduced in the CLP Regulation in 2023. [Commission Delegated Regulation \(EU\) 2023/707](#) amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures, adopted on 19 December 2022, published in the Official Journal of the European Union on 31 March 2023, and entered into force on 20 April 2023. For PMT substances, the mobility criterion shall be considered fulfilled when the $\log K_{oc}$ is less than 3; for an ionisable substance, the mobility criterion shall be considered fulfilled when the lowest $\log K_{oc}$ value for pH between 4 and 9 is less than 3. For a vPvM substance, the very mobile criterion shall be considered fulfilled when the $\log K_{oc}$ is less than 2; for an ionisable substance, the mobility criterion shall be considered fulfilled when the lowest $\log K_{oc}$ value for pH between 4 and 9 is less than 2. The persistence and toxicity criteria are similar to those set out in REACH Annex XIII. The new rules for the classification and labelling of PMT and vPvM substances will apply to new substances from 1 May 2025 (and from 1 November 2026 for substances placed on the market before 1 May 2025). For new mixtures placed on the market, requirement will apply from 1 May 2026 (1 May 2028 for mixtures placed on the market before 1 May 2026).

Following the introduction of the new hazard classes PMT/vPvM substances, a number of regulations using CLP hazard classes for triggering risk management measures were

expected to be revised. The inclusion of PMT/vPvM substances as categories of SVHCs in Article 57 of REACH was announced in the CSS. Delays in the preparation of the Commission proposal for the revision of the REACH Regulation, which will likely not be published before the nomination of the next Commission in 2024, have not allowed this action item of the CSS to be completed this year. PMT/vPvM hazard classes have however already been used for triggering risk management measures. In its proposal for a Directive on the Union code relating to medicinal products for human use, published in April 2023, the Commission proposed to subject to medical prescription medicinal products containing active substances classified as PMT and vPvM (Article 51 of COM(2023) 192 final). The proposed Directive is currently undergoing legislative procedure and this measure might not be adopted as such in the final text.

Revision of the CLP Regulation

In addition to the delegated act establishing the new hazard classes, the CLP Regulation was also revised through legislative procedure. The European Parliament and the Council adopted the [final agreement](#) on the revised Regulation on 20 December 2023.

To accelerate the adoption of harmonised classifications, the revised Regulation gives the possibility to the Commission to request ECHA and EFSA to prepare a harmonised classification proposal, which previously was only provided to Member States competent authorities and manufacturers, importers and downstream users. In addition, ECHA and EFSA are enabled to provide, on their own initiative, scientific advice to the Commission and Member States on which substances or group of substances should have harmonised classification. As proposed by the European Parliament, the revised Regulation explicitly calls for the prioritisation of groups of substances over individual substances in proposals for harmonised classification and labelling whenever feasible. In such case, the Regulation provides that ‘substances shall be grouped together based on clear scientific reasoning taking into account how the available information 1) supports the grouping of substances and 2) allows the property(ies) of the substance(s) to be reliably predicted from other substances in the group’.

To avoid duplication with ongoing assessments that are currently conducted under different pieces of legislation, the Regulation provides that delegated acts should be adopted within 18 months to include in Part 3 of Annex VI (hazardous substances for which harmonised classification and labelling have been established at EU level) for substances added to the Candidate list and substances for which a decision on the application for approval or the renewal of approval has been made under PPPR and BPR.

The revised Regulation provides a mandate for the Commission to promote at UN level the harmonisation of the criteria for classification and labelling of endocrine disruptors, PBT, vPvB, PMT, vPvM, the adaptation of criteria for alternative approaches, in particular non-animal test methods, and the assessment of the need for new criteria for immunotoxic and neurotoxic substances. New provisions also aim to speed up the integration into CLP of alternative approaches for the classification of substances and mixtures, in particular non-animal test methods, preferably no later than 18 months after non-animal data are included in harmonised criteria at UN level.



Adoption of new F-gas Regulation

The Council and European Parliament reached a [provisional agreement](#) on the revision of the F-gas Regulation on 19 October 2023. The agreement provides for a complete phase out of HFC consumption by 2050. Production rights allocated by the Commission will be gradually phased down from 2024 to 2049. The agreement includes specific phase-out dates for the use of F-gases in certain products, including key sources of PFAS emissions: heat pumps and air conditioning units must use F-gas free alternatives by 2035 and medium and high voltage switchgear by 2030 and 2032.

Adoption of the Regulation on reporting of environmental data from industrial installations and establishing the Industrial Emissions Portal

The European Parliament and the Council adopted the [provisional agreement](#) on the Industrial Emissions Portal (replacing the European Pollutant Release and Transfer Register (E-PRTR)) on 29 November 2023. The Regulation requires certain industries (installations subject to IED, mining, UWWTPs, aquaculture, shipbuilding) to report their releases of certain pollutants (listed in Annex II) to air, water and soil, when they are above a certain threshold. The addition of PFOA and its salt and PFHxS and its salts to the list of pollutants which have to be reported, with thresholds set at 1kg/year released to air, water and land, has been maintained in the final text of the Regulation.

The Regulation also defines the list of pollutants that can be added to Annex II, which includes: substances identified as SVHCs or addressed in REACH restrictions; designated as priority substances under the Water Framework Directive and EQS Directive; substances included in the watch lists of the Groundwater Directive, the EQS Directive and the Drinking Water Directive; subject to limit values or other restrictions under the Ambient Air Quality Directive, Directive 2004/107/EC on the concentrations of certain pollutants in ambient air, the Groundwater Directive and the Drinking Water Directive. The final text also includes the possibility to remove pollutants that are no longer designated as priority substances. The Regulation will enter into force in 2028.

Adoption of the revised Industrial Emissions Directive

The European Parliament and the Council adopted the [provisional agreement](#) on the revision of the Industrial Emissions Directive on 29 November 2023.

Installations covered by IED

The scope of the Industrial Emissions Directive is extended to cover extractive industry installations (mines) and large installations manufacturing batteries. Regarding livestock farms, cattle farms are kept out of the scope of the Directive entirely; pigs and poultry farms are covered by the Directive but thresholds have been significantly raised compared to the initial Commission proposal of 150 livestock units (LSU).

Permit conditions (Article 14)

The New Directive revises and makes stricter a number of the permit conditions that are laid down in Article 14. While the previous Directive contained a non-exhaustive list of polluting substances for which emission limit values should be set, the new Directive refers to Annex II to the Industrial Emissions Portal Regulation and requires that permits



contain emission limit values for those substances which are likely to be emitted from the installation. Compared to the previous system, the list of substances concerned is more specific and can be amended more easily. A requirement to assess the need to prevent or reduce the emissions of SVHCs and substances addressed in REACH restrictions; measures to protect drinking water abstraction points; and appropriate requirements for the periodic monitoring of soil, surface and groundwater in relation to relevant hazardous substances likely to be found on site are new elements that should be included in the permit.

Environmental management system (EMS) (Article 14a)

The new Directive introduces an obligation for operators to implement an environmental management system, which must contain a chemicals inventory of the hazardous substances present in or emitted from the installation, a risk assessment of the impacts of these substances on human health and the environment, and an assessment of the possibilities to substitute them with safer alternatives.

Setting emission limit values (Article 15)

The proposal from the Commission that competent authorities should set the emission limit values at the lowest end of the relevant BAT-AEL range, which aimed to harmonised the emission limit values across Member States, was not maintained in the final text. Instead, competent authorities should set 'the strictest achievable emission limit values by applying BAT in the installation, considering the entire range of the emission levels associated with the best available techniques (BAT-AELs)'.

Stricter conditions to meet EQS (Article 18)

The general principle that where an environmental quality standard requires stricter conditions than those achievable by the use of the BAT, additional measures shall be included in the permit, is maintained in the final agreement. The requirement for the operator of the installation, when stricter conditions have been included in the permit, to monitor the concentration of relevant pollutants in the receiving environment is removed and replaced by a requirement for the competent authority to assess the impact of the stricter conditions on the concentration of the pollutants concerned in the receiving environment. In addition, 'where the load of pollutants emitted by the installation has a quantifiable or measurable effect on the environment, Member States shall ensure that the concentration of the pollutants concerned in the receiving environment is monitored'. The results of the monitoring should be transmitted to the competent authority.

Access to justice (Article 79a)

The general principle that individuals affected by damage to human health resulting from the violation of the national measures transposing the IED have the right to claim and obtain compensation is maintained in the final text. Provisions enabling NGOs to represent affected individuals and bring collective actions for compensation, as well as provision establishing a reversed burden of proof (i.e. the person responsible for the violation must prove that the violation did not cause or contribute to the damage) have however been deleted from the final agreement.



Transitional periods

The Directive provides for transitional periods for competent authorities and operators to comply with the new provisions of the Directive: 12 years for existing activities and 10 years for new activities.

Adoption of the Ecodesign for Sustainable Products Regulation (ESPR)

The European Parliament and the Council adopted the [provisional agreement](#) on the new Ecodesign Regulation on 19 December 2023. The Regulation establishes the general framework allowing the Commission to establish ecodesign requirements (performance and information requirements) for products through subsequent regulations specific to product groups. Performance requirements may be adopted to restrict the use of substances of concern during the manufacturing process of a product and/or the presence of such substances in the final product, primarily if these substances impede the reuse or recycling of the product.

The Regulation defines substances of concern as:

- 1) substances identified as SVHCs under REACH,
- 2) substances with certain CLP classifications (CMR 1 and 2; endocrine disruptors for human health and environment 1 and 2; PBT, vPvB; PMT, vPvM; respiratory sensitiser 1; skin sensitiser 1; hazardous to the aquatic environment categories 1 to 4; hazardous to the ozone layer; toxic for a specific target organ - repeated and single exposure 1 and 2) and substances regulated under the POPs Regulation and,
- 3) substances that negatively affects the re-use and recycling of materials in the product in which it is present.

The Commission will be tasked to determine, for each product group, which substances fall under this definition before ecodesign requirements can be adopted, taking into account at least, whether:

- a) based on standard technologies, the substances make the re-use, or recycling process more complicated, costly, environmentally impactful, or energy- or resource-demanding;
- b) the substances impair the technical properties or functionalities, the usefulness or the value of the recycled material or products manufactured from this recycled material;
- c) the substances negatively impact aesthetic or olfactory properties of the recycled material.

Information requirements will enable the tracking of all substances of concern throughout the life cycle of products and contain the name of the substances of concern (IUPAC or another international name), their EC and CAS numbers, the location of the substances within the product, the concentration, maximum concentration or concentration range of the substances of concern, at the level of the product, its relevant components, or spare parts; relevant instructions for the safe use of the product; information relevant for disassembly, preparation for reuse, reuse, recycling and the environmentally sound management of the product at the end of its life. The required



information will be provided either on the product or be accessible through the digital product passport. The Commission may set thresholds from which information requirements may apply.

The purpose of performance and information requirements related to substances of concern is primarily to increase product circularity and recyclability. The Regulation specifies that performance requirements ‘shall not restrict the presence of substances in products for reasons relating primarily to chemical safety’, which is regulated by the REACH Regulation. It however raises questions as to how this distinction will be made consistently. Information requirements aim to ensure that information on hazardous chemicals present in the product is still accessible at the time the product is reused or recycled. Possible overlaps with reporting requirements under the Waste Framework Directive (SCIP database) for SVHCs will also likely come up as an issue in the adoption of information requirements under the ESPR.

The Regulation establishes work programme for the adoption of ecodesign criteria, which prioritises product groups and is revised every three years. The first programme, to be adopted no later than 9 months after the entry into force of this Regulation, should focus on iron, steel, aluminium, textiles, furniture, tyres, detergents, paints, lubricants, chemicals, energy related products, ICT products and other electronics.

Main ongoing initiatives to follow in 2024

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 and may be adopted in 2024.

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, and the restriction may be adopted in 2024.

Revision of the Urban Wastewater Treatment Directive

The Commission published a proposal for the revision of the Urban Wastewater Treatment Directive in October 2022. In 2023, both the European Parliament and the Council have adopted their negotiating positions. An agreement is likely to be reached in 2024 before the European elections.



Revision of the Regulation on Packaging and Packaging Waste

The Commission published the proposal for a Regulation on Packaging and Packaging Waste, replacing the former Packaging and Packaging Waste Directive, in November 2022. In 2023, both the European Parliament and the Council have adopted their negotiating positions. The European Parliament proposed to ban the placing on the market of food packaging containing intentionally added PFAS. An agreement is likely to be reached in 2024 before the European elections.

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. The Council has not yet reached a general approach; progress on this is expected in 2024. Interinstitutional negotiations and an agreement on the final text are however unlikely to happen before the new Parliament and Commission are in place at the end of 2024.

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 is expected to adopt its position in April 2024. Interinstitutional negotiations and an agreement on the final text are however unlikely to happen before the new Parliament and Commission are in place at the end of 2024.

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. Work on the proposed text is ongoing in both institutions. The European Parliament is expected to adopt its position in April 2024. Interinstitutional negotiations and an agreement on the final text are however unlikely to happen before the new Parliament and Commission are in place at the end of 2024. In addition, according to the EU soil strategy for 2030, a priority list of contaminants posing significant risk for soil quality should be developed in 2024.

‘One Substance, One Assessment’ legislative package

The Commission adopted on 7 December 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 feedback period on the three proposed acts is ongoing until early March 2024.

Proposal for the revision of the REACH Regulation

The proposal for the revision of the REACH Regulation, announced in the Chemicals Strategy for Sustainability, and postponed to the last quarter of 2023, was not published last year. The REACH revision is not listed in the Commission work programme for 2024, adopted on 17 October 2023, indicating that the proposal is unlikely to be published under the current Von der Leyen Commission.





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