

The real risk of each substance needs to be carefully assessed

With the endorsement of the ideals of the toxic-free and pollution-free environment, EU chemical regulation is evolving rapidly and becoming more and more precautionary, moralistic, and, consequently, unhinged. The proposed restriction on thousands of diverse substances under the label of 'all PFAS' through the broadest ban on chemicals ever is illustrative of these trends.

The PFAS proposal flies in the face of science-based risk regulation, breaches the law, and deters innovation and investment in the EU. One of the most vexing problems associated with the PFAS Proposal relates to the unscientific use of the 'grouping approach,' which throws all subgroups of PFAS substances on the same pile based merely on a common moiety, without regard to hazard, risk, and exposure profiles. Another serious deficiency involves the equating of persistence (which is merely a pejorative way to characterize durability) with risk and even harm. The combination of persistence as harm with broad, open-ended grouping spreads and augments the adverse effects of the PFAS restriction.

This proposal would not only make a mockery of science-based chemical risk regulation, but also set aside the essential safeguards set forth in the REACH Regulation and imposed by EU law. In essence, the grouping based solely on structural similarity reflects dogmatic thinking inspired by the precautionary principle and the naturalistic fallacy — 'only biodegradable is good'. The main purpose of this paper is to explain how the proposal is neither science-based nor compliant with the applicable legal requirements.

The PFAS Proposal, which targets over 10,000 different substances, treats a known desirable property, durability, as an unknown potential harm that must be prevented at all costs and irrespective of the risks associated with the withdrawal of substances and the widespread introduction of alternatives. Undisciplined reading across from some hazardous PFAS substances, such as PFOS and PFOA, to all PFAS substances, however, would result in overly broad, unnecessary, and disproportionate regulation.

The default assumption under the REACH Regulation is that chemicals are regulated substance-by-substance, based on substance-specific careful risk assessment, assessment of alternatives, and socio-economic impact analysis, subject only to grouping under strict conditions. This fundamental principle is perverted in the PFAS proposal. Despite the proposal's many pages and extensive annexes, risk assessments are unavailable for the vast majority of PFAS, assessments of alternatives are poorly supported with evidence or even entirely lacking, and the impact analysis is rudimentary at best.

The problematics of this proposed restriction are not limited to PFAS – it is

indicative of the current trends in chemical risk regulation and would set a precedent that does not bode well for future regulatory proposals. As the PFAS Proposal demonstrates, European governments have discovered the potential of persistence as a vehicle to phase-out large groups of chemicals in pursuit of “toxic-free” society and “pollution-free” environment. Following incidents in the US and Europe, PFAS is an easy target and now serves as the test case for this novel approach. This proposal therefore should be of great concern to all stakeholders that care for balanced, science-based chemical risk regulation in accordance with the law.

Thorough analysis of the issues associated with the PFAS proposal suggests that the EU has incrementally moved towards chemical regulation based on an ideal of rooting out any chemical risk, and increasingly ignores the growing problem of false positives, risk/risk trade-offs (the risks of existing substances with which there is experience versus the risks of replacement substances that are largely unknowns) and the environmental, human health and economic consequences of the “zero risk” approach. Rather than preventing “regrettable substitution,” the proposal would result in regrettable stigmatization and, indeed, may increase, rather than prevent, risks of regrettable substitution.

Instead of the dogmatic approach reflected in the PFAS Proposal, the EU should follow the chemical risk regulation model embedded in the REACH Regulation, group PFAS in a way that reflects science and regulatory requirements, target risks that are unacceptable, and carefully weigh the costs and benefits of alternative regulatory measures and their real-world effects. In short, it should return to chemical risk management based on the tested principles of science-based risk assessment and relative cost-benefit analysis of available risk management options.