The problematics of the proposed PFAS restriction – science, law, and policy

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This submission, which reflects solely the author's own analysis and opinions, discusses general and specific issues associated with the proposed PFAS restriction ("PFAS proposal") in the context of the ideal of a 'toxic-free' society and science-based chemical risk regulation pursuant to the REACH Regulation. It comprises four parts:

- The first part reviews the recent evolution of EU chemical risk regulation in the context of the EU Green Deal.
- The second part summarizes the main features of the proposed PFAS restriction.
- The third part analyzes the problematics associated with the proposal.
- The fourth part presents conclusions.

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Dr. Bergkamp co-edited and co-authored the Encyclopedia on *Chemical Risk Governance* published by Edward Elgar (2023),[1] edited and co-authored a treatise on the *REACH Regulation* published by Oxford University Press (2013),[2] was a contributor to *Persistent, Bioaccumulative, and Toxic (PBT) Chemicals: Technical Aspects, Policies, and Practices* published by Taylor & Francis (2016),[3] and published many articles on chemical regulation,

[1] Abelkop A., Bergkamp L., Bergeson L., Auerbach B. (editors), Chemical Risk Governance, Elgar Encyclopedia of Environmental Law, Vol. XII, Elgar, 2023.
[2] Bergkamp L (editor), The European Union REACH Regulation for Chemicals: Law and Practice. Oxford University Press, 2013.
[3] Abelkop A.D.K., Graham J.D., Royer, T.V., Persistent, Bioaccumulative, and Toxic (PBT) Chemicals: Technical Aspects, Policies, and Practices, CRC Press, Taylor & Francis, 2016.

risk regulation, the precautionary principle, and legal issues associated with risk governance and regulation.[4]

This submission is an extract from a working paper on EU chemical regulation and the proposed PFAS regulation on which the author is currently working.

The author wishes to thank the scientists and lawyers who have been willing to provide feedback on earlier drafts of this paper. Only the author is responsible for any remaining errors or omissions.

Comments on this paper and questions are welcome and may be sent to [redacted]@proximus.be.

[4] See, for instance, Bergkamp L. & Abelkop A., Chemicals Regulation, in: Emma Lees (ed.), Jorge E. Viñuales (ed.), The Oxford Handbook of Comparative Environmental Law, 2019, Chapter 26. Bergkamp L. & Herbatschek N., Regulating Chemical Substances under REACH: The Choice Between Authorization and Restriction and the Case of Dipolar Aprotic Solvents, Review of European Community and International Environmental Law, 2014, pp. 221-245. Bergkamp L. & Hanekamp J.C., REACH and the precautionary principle: costs and benefits of proposed chemical regulation, in: K. Okonski & J. Morris (editors), Environment & Health: Myths & Realities, International Policy Press, 2004, pp. 138-165.

Summary

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.

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1. Introduction

In February, the European Chemicals Agency (ECHA) published a proposed restriction of per- and polyfluoroalkyl substances (PFASs).[5] PFASs are a diverse class of synthetic chemicals, which includes gases, liquids, and solid high-molecular weight polymers. They are used in many applications and products, varying from automotive and aviation to food contact materials, textiles, construction and household products, electronics, firefighting foams, and medical articles. As ECHA acknowledges, PFASs have unique desirable properties, such as excellent stability under intense heat and water and grease repellents.[6] Concerns have emerged, however, that they are environmental pollutants and may be linked to negative effects on human health.[7] To address these concerns, a wide-ranging restriction with limited exceptions has been proposed.

The proposed PFAS restriction ("PFAS proposal"), which the proponents also call, appropriately, the "universal PFAS restriction,"[8] raises important issues around the regulation of chemical risks. It is illustrative of a broader set of problems that plagues risk regulation[9] and raises specific issues in relation to a large group of substances labelled as PFASs. This paper discusses the PFAS restriction proposal in the context of the toxic-free society. It analyzes the costs and benefits of this proposed regulation and attempts to derive general lessons from this analysis for chemical regulation. It comprises four parts.

Part 1 discusses the background against which the PFAS proposal should be understood. EU chemical regulation is evolving rapidly and the proposed PFAS restriction reflects this evolution. Part 2 briefly reviews the key features of the proposal, covering the definition of PFAS, the grouping approach, and persistence, among other features. In the third part, these features are analyzed in more detail with a view to understanding their coherence and

[5] ECHA News, ECHA publishes PFAS restriction proposal, ECHA/NR/23/04, 7 February 2023, https://echa.europa.eu/-/echa-publishes-pfas-restriction-proposal
[6] ECHA, Per- and polyfluoroalkyl substances (PFAS), https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas
[7] Fenton SE, Ducatman A, Boobis A, DeWitt JC, Lau C, Ng C, Smith JS, Roberts SM. Per- and Polyfluoroalkyl Substance Toxicity and Human Health Review: Current State of Knowledge and Strategies for Informing Future Research. Environ Toxicol Chem. 2021 Mar;40(3):606-630. http://doi:10.1002/etc.4890 (noting that "[c]urrently, much of the toxicity data available for PFAS are for a handful of chemicals, primarily legacy PFAS such as perfluorooctanoic acid and perfluorooctane sulfonate").
[8] The Annex XV dossier states that "human exposure is likely underestimated when only taking known PFASs into consideration, and emphasise the need for a universal PFASs restriction to protect human health." PFAS Proposal, p. 47.
[9] BERGKAMP, L. (2017). The Reality of Risk Regulation. European Journal of Risk Regulation, 8(1), 56-63. doi:10.1017/err.2016.9

implications. In addition to the fitness for purpose of the PFAS definition, the concepts of grouping to avoid regrettable substitution and persistence as harm are critically reviewed. An assessment is made of the costs and benefits of the PFAS proposal and the way in which the proponents have dealt with these issues. Part 4 presents conclusions.

a. PFAS, adverse effects, and proposed restriction

PFAS substances (PFASs) derive their desirable properties from strong carbon-fluorine bonds, which causes them to be resistant to degradation. The lack of degradation, however, is also viewed as a concern if PFASs are emitted into the environment. These issues arise in particular in the case of long-chain PFASs. Furthermore, some PFASs are mobile and can be transported over long distances from the point of release. PFASs have been detected in groundwater and drinking water.[10] Specific PFASs have also been associated with bioaccumulation[11] and adverse health effects, such as reprotoxic, carcinogenic and endocrine effects, but any such adverse effects are subject to intense scientific debate.[12] Industry has developed alternatives to PFASs. Some of these alternative PFAS substances are non-hazardous and replaced substances such as chlorofluorocarbons (CFCs) and hydrochlorofluorocarbons (HCFCs), which are ozone-depleting substances and have been phased out pursuant to the Montreal Protocol.[13] Other alternative PFASs, however, also turned out to be hazardous to human health and the environment.[14] Despite the continuing development of alternatives, however, the focus of European regulatory authorities shifted to other and eventually to all PFASs.

Releases of PFASs may occur from sources such as professional and industrial facilities using PFAS, and during use of consumer products, such as cosmetics, clothing, and food contact materials (including coating of non-sticking frying pans, pesticides and medicinal products). Human beings may be exposed to low concentrations of PFAS at home, in the workplace, or through the environment.[15] One common route of exposure is from foodstuffs and drinking

[10] Christy A. Barlow, Cynthia A. Boyd, Megan J. Kemp, Kimberly A. Hoppe Parr, PFAS Toxicology: What is Driving the Variation in Drinking Water Standards?, GZA, Boulder, June 2019, https://portal.ct.gov/-/media/DEEP/PFASTaskForce/HHCBarlowBoydKempHoppeParr2019PFASToxicologypdf.pdf

[11] Kevin C Jones, Persistent Organic Pollutants (POPs) and related chemicals in the global environment: some personal reflections, Environ. Sci. Technol. 2021, 55, 14, 9400–9412, https://doi.org/10.1021/acs.est.0c08093 ("We all have a baseline of POPs residues in our tissues, even the unborn fetus via placental transfer and the newly born baby via mother's milk.")

[12] Kevin C Jones, Persistent Organic Pollutants (POPs) and related chemicals in the global environment: some personal reflections, Environ. Sci. Technol. 2021, 55, 14, 9400–9412, https://doi.org/10.1021/acs.est.0c08093 ("Depending on which papers you read, POPs may be relatively benign, or they could be responsible for key subchronic and chronic effects on reproductive potential, on immune response, as carcinogens, and on a range of behavioral and cognitive end points.")

[13] Montreal Protocol on Substances that Deplete the Ozone Layer, adopted on 16 September 1987, https://treaties.un.org/doc/publication/unts/volume%201522/volume-1522-i-26369-english.pdf

[14] Yao Lu, Yong Liang, Zhen Zhou, Yawei Wang, and Guibin Jiang, Possible Fluorinated Alternatives of PFOS and PFOA: Ready to Go?, Environ. Sci. Technol. 2019, 53, 24, 14091–14092.

[15] De Silva, A.O., Armitage, J.M., Bruton, T.A., Dassuncao, C., Heiger-Bernays, W., Hu, X.C., Kärrman, A., Kelly, B., Ng, C., Robuck, A., Sun, M., Webster, T.F. and Sunderland, E.M. (2021), PFAS Exposure Pathways for Humans and Wildlife: A Synthesis of Current Knowledge and Key Gaps in Understanding. Environ Toxicol Chem, 40: 631-657. https://doi.org/10.1002/etc.4935

water.[16] Exposure, of course, is a necessary, but insufficient condition for risks of adverse effects due to intrinsic properties of PFASs.

The PFAS restriction proposal was prepared by authorities of Denmark, Germany, the Netherlands, Norway and Sweden.[17] The proposal is over 200 pages and there are seven annexes. The objective is to substantially reduce the emission of PFASs into the environment and phase out and eliminate uses of PFASs;[18] they did not consider to any significant extent the question whether alternatives to PFASs would fare any better from an environmental and health protection perspective. As drafted, the PFAS proposal covers over 10,000 substances, as well as an open-ended category of theoretical PFAS substances.[19] All of these substances are believed to be either very persistent themselves, or to degrade into very persistent PFASs in the environment. The proposal does not cover the use of PFASs in firefighting foams, which is covered by a separate restriction proposal.[20]

In all respects, the scope of the PFAS proposal is uniquely broad. The proposed restriction would apply to the manufacture, placing on the market, as well as the use of PFASs as such and as constituents in other substances, in mixtures and in articles (i.e., any products) above a specified concentration limit. All uses of PFASs would be covered by the restriction, irrespective of whether they have been specifically assessed or are referenced in the proposal, unless a specific derogation applies.[21]

The proponents considered two regulatory options: a full ban with no derogations and a transition period of 18 months, and a full ban with use-specific time-limited derogations (18-month transition period plus either a five- or 12-year derogation period).[22] The proposed derogations and their duration are based on the availability and applicability of alternatives to PFASs. Some derogations are tentative, as the evidence base was found to be too weak to reach a firm conclusion; if companies do not provide substantial evidence, the proposed derogation will be deleted.[23]

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[16] Fromme, H., et al., Perfluorinated compounds – Exposure assessment for the general population in western countries. International Journal of Hygiene and Environmental Health, 2009, 212: 239-270 (PFOAs (perfluorooctanoic acid) and PFOSs (perfluorooctanesulfonic acid) exposure occurs for 99% and 96%, respectively, via food.) José L. Domingo, Martí Nadal, Human exposure to per- and polyfluoroalkyl substances (PFAS) through drinking water: A review of the recent scientific literature, Environmental Research, Volume 177, 2019, 108648, ISSN 0013-9351, https://doi.org/10.1016/j.envres.2019.108648

[17] ECHA, Annex XV Restriction Report Per- and polyfluoroalkyl substances (PFASs), Version number 2, 22 March 2023, https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49 ("PFASs proposal")

[18] For an overview of the uses of PFAS, see Juliane Gluge, et al., An overview of the uses of per- and polyfluoroalkyl substances (PFAS), Environ. Sci.: Processes Impacts, 2020,22, 2345-2373, https://doi.org/10.1039/D0EM00291G

[19] "The substance scope also includes theoretical substances that are likely never to have been on the market." PFASs Proposal, p. 14.

[20] ECHA, Annex XV Restriction Report Per- and polyfluoroalkyl substances (PFASs) in firefighting foams, Version number 2, 22 March 2023, https://echa.europa.eu/documents/10162/4524f49c-ae14-b01b-71d2-ac3fa916c4e9

[21] PFASs Proposal, p. 2.

[22] This second option also includes time unlimited, general derogations for PFASs used as active substances in plant protection products, biocidal products and human and veterinary medicinal products, which are assessed under separate specific regulations.

[23] PFASs Proposal, p. 3.

In March 2023, a six-month consultation on the proposal commenced. The ECHA's Risk Assessment Committee (RAC) and Committee for Socio-Economic Analysis (SEAC) have begun their evaluation of the proposal and are expected to issue their opinions later this year. RAC will form an opinion on whether the proposed restriction is appropriate in reducing the risks to people's health and the environment, while SEAC's opinion will be on the socio-economic impacts, i.e., benefits and costs to society, associated with the proposal. Both committees form their opinions based on the information in the restriction proposal and the comments received during consultations. The committees also consider advice from the Enforcement Forum on the enforceability of the proposed restriction. Once the opinions are adopted, they will be sent to the European Commission which, together with the EU Member States, will then decide on the potential restriction.

b. The toxic-free society, zero pollution, and new regulatory concepts

As ECHA's Director for Risk Assessment confirmed, the PFAS proposal is a "landmark proposal" that "supports the ambitions of the EU's Chemicals Strategy and the Zero Pollution action plan."[24] Indeed, the approach that underlies the proposed restriction breathes the EU's ambitious Green Deal, billed as the "EU's new growth strategy."[25] In its 2019 communication, the European Commission, referring to a "zero pollution ambition for a toxic-free environment," explained that "[c]reating a toxic-free environment requires more action to prevent pollution from being generated as well as measures to clean and remedy it."[26] To achieve full protection of citizens and ecosystems and remedy any pollution, all policies and regulations would need to be systematically reviewed.

In the Chemicals Strategy for Sustainability, the Commission articulated its ambition "to develop and deploy the sustainable chemicals that enable the green and digital transitions and to protect environment and human health, in particular that of vulnerable groups, innovation for the green transition of the chemical industry and its value chains must be stepped up and the existing EU chemicals policy must evolve and respond more rapidly and effectively to the challenges posed by hazardous chemicals."[27] As part of this initiative,

[24] ECHA News, ECHA publishes PFAS restriction proposal, ECHA/NR/23/04, 7 February 2023, https://echa.europa.eu/-/echa-publishes-pfas-restriction-proposal
[25] European Commission, Industry and the Green Deal, https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal/industry-and-green-deal_en
[26] Communication from the European Commission, The European Green Deal, COM/2019/640 final, https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1576150542719&uri=COM%3A2019%3A640%3AFIN
[27] Communication from the European Commission, Chemicals Strategy for Sustainability, COM(2020) 667 final, Brussels, 14.10.2020, https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf ("Chemicals Strategy for Sustainability" or CSS). For a powerful critique of the CSS, see Matthias Herzler et al. (German Federal Institute for Risk Assessment, BfR), The "EU chemicals strategy for sustainability" questions regulatory toxicology as we know it: is it all rooted in sound scientific evidence?, Archives of Toxicology (2021) 95:2589–2601, https://doi.org/10.1007/s00204-021-03091-3 For further discussion, see Frank A. Barile, et al., The EU chemicals strategy for sustainability: in support of the BfR position, Archives of Toxicology, 2021, https://doi.org/10.1007/s00204-021-03125-w For a similar critical analysis, see James W. Bridges, Helmut Greim, Kees van Leeuwen, Rainer Stegmann, Theo Vermeire, Klaas den Haan, Is the EU chemicals strategy for sustainability a green deal?, Regulatory Toxicology and Pharmacology, Volume 139, 2023, 105356,

chemicals having a chronic effect would have to be "minimised and substituted as far as possible," with the most harmful ones being phased out for non-essential societal uses."[28]

i. Generic approach and essential use

The Chemical Strategy for Sustainability proposes two key regulatory concepts to achieve a toxic-free society. The first one is the "generic approach to risk management," which has been applied to ban carcinogenic substances generally from most consumer products, in particular for uses that expose vulnerable groups.[29] This "preventive approach" is deemed to be "simpler" and "generally faster" than specific risk regulation. The Commission intends to apply this approach as "the default option" and to extend it to risk management of substances that "cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative."[30] The idea is that doing so would ensure more consistent protection of the consumers, vulnerable groups and the natural environment, "while still allowing for the use of these most harmful chemicals where proven essential for society." Generic risk management would be facilitated by a novel, liberal grouping approach.[31]

"Essential use" thus is the second key regulatory concept. This concept has been implemented through the Montreal Protocol on Substances that Deplete the Ozone Layer. Criteria would have to be developed to define "essential uses" and ensure consistent application across the EU and various sectors. The objective would be "to ensure that 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."[32]

The introduction of these novel concepts requires legislation, which is being prepared. Given that the legislative process takes time, the Commission has taken the position that as long as the generic approach to risk management is not in place, substances of concern should be "prioritized for restrictions for all uses and through grouping, instead of regulating them one by one."[33] The Commission does not explain how this can be accomplished in a way that is consistent with the current legislative frameworks.[34] Nevertheless, both the

https://doi.org/10.1016/j.yrtph.2023.105356,
https://www.sciencedirect.com/science/article/pii/S0273230023000247

[28] For a defense of the CSS, see Millstone, E., & Clausing, P. (2023). Reasons for Reinforcing the Regulation of Chemicals in Europe. European Journal of Risk Regulation, 14(1), 78-92. doi:10.1017/err.2022.41

[29] Restrictions and bans apply to products such as food contact materials, toys, childcare articles, cosmetics, detergents, furniture and textiles.

[30] Chemicals Strategy for Sustainability, p. 10. The Commission has launched "a comprehensive impact assessment to define the modalities and timing for extending the same generic approach, with regard to consumer products, to further harmful chemicals, including those affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ."

[31] See further Sections 2.d and 3.b.ii, below.

[32] Chemicals Strategy for Sustainability, p. 10.

[33] Chemicals Strategy for Sustainability, p. 10.

[34] The concept of a "generic approach to risk management" is controversial and not part of the legislative framework. Likewise, the application of the proposed concept of "essential use" is disputed and not part of the current law.

generic approach and essential use concepts provide explanations for the structure and content of the PFAS proposal.

ii. Mixtures and combined effects

Several chemical substances may cause the same environmental or health effect, which raises the question as to how exposure to such substances should be regulated to avoid synergistic adverse effects. The issue of potential combined effects of exposure to chemicals has been on the EU's agenda for some time. In 2016, EFSA explored risk assessment methodologies for human health and ecological risk assessment of combined exposure to multiple chemicals.[35] In 2019, EFSA published guidance on such methodologies.[36] This guidance discusses component-based approaches, including the grouping of chemicals into common assessment groups, the use of dose addition as a default assumption, and approaches to integrate evidence of interactions. EFSA's Scientific Committee considers this Guidance fit for purpose for risk assessments of combined exposure to multiple chemicals.

In response to calls from stakeholders,[37] the Chemical Strategy for Sustainability has also identified the issue of exposure to a mix of chemicals from various sources. It observes that "the safety of chemicals in the EU is usually assessed through the evaluation of single substances, or in some cases of mixtures intentionally added for particular uses, without considering the combined exposure to multiple chemicals from different sources and over time."[38] Some environmental and food contact laws[39] require that the cumulative exposure to the same or similar chemicals from different sources be assessed. There is no structural assessment, however, of the impact of unintentional mixtures.

According to the Commission, regulation should systematically address the risks of combined effects of exposure to multiple chemicals across chemicals-related policy areas. Since "it is currently not realistic nor economically feasible to specifically assess and regulate an almost infinite number of possible combinations of chemicals," the Commission opines that methodologies should be developed for assessment of combined effects of chemical mixtures. Apparently in an attempt to circumvent the lack of assessment methods, the Commission is committed to assess "how to best introduce in REACH (a) mixture assessment

[35] EFSA, Public consultation on the terms of reference of the Scientific Committee Working Group on "Harmonisation of risk assessment methodologies for human health and ecological risk assessment of combined exposure to multiple chemicals", 25 October 2016, https://www.efsa.europa.eu/en/consultations/call/161024a

[36] EFSA Scientific Committee, Simon John More et al., Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals, EFSA Journal, Volume17, Issue3, March 2019, e05634

[37] See, e.g., Kortenkamp, Andreas, Faust, Michael, Regulate to reduce chemical mixture risk, Science 361, 224-226 (2018), DOI:10.1126/science.aat9219 ("Scientific evidence for heightened toxicity from such mixtures is mounting, yet regulation is lagging behind. Ensuring appropriate regulation of chemical mixture risks will require stronger legal stimuli as well as close integration of different parts of the regulatory systems in order to meet the data and testing requirements for mixture risk assessment.")

[38] Chemicals Strategy for Sustainability, p. 10.

[39] The EU legislation concerning plant protection products and biocides require that consideration is given to cumulative and synergistic effects.

factor(s) for the chemical safety assessment of substances."[40] A mixture assessment factor (MAF) is "an additional safety factor that can be applied in the risk assessment of single chemicals, in order to generically cover for combined exposure without performing a mixture-specific assessment."[41] In other words, a MAF is a simple, rough-and-dirty way to address the issue of combined effects without doing any assessment.

iii. Innovation and 'Safe and Sustainable by Design'

According to the Commission, research and innovation plays a key role in "driving transformative change" and modernising the EU economy and society to "re-orient them towards a just and sustainable future."[42] As part of this vision, the European Commission believes that products and chemical substances should meet more stringent standards in relation to safety and sustainability. A proposal for a new Ecodesign for Sustainable Products Regulation would become the cornerstone of the EU's approach to more environmentally sustainable and circular products.[43]

1) Sustainable chemistry

Pursuant to this Regulation, ecodesign requirements could be set for a series of aspects, including the presence of "substances of concern," defined to include substances on the REACH Candidate List, all substances classified as hazardous, as well as any substance that "negatively affects the re-use and recycling of materials in the product in which it is present."[44] The Regulation would authorize the restriction of substances present in products or used in their manufacturing processes that negatively affect products' sustainability, primarily for reasons other than chemical or food safety. In addition, it would enable the imposition of requirements for disclosing the presence of substances and tracking their presence throughout the life cycle of materials and products.

In line with this legislative proposal, the Commission's Chemicals Strategy for Sustainability not only calls for "minimising the presence of substances of concern in products, and ensuring the availability of information on chemical content and safe use,"[45] but also emphasizes the societal urgency of a "transition to chemicals that are safe and sustainable by design."[46] The desired transition would also be an economic opportunity "for the EU

[40] Chemicals Strategy for Sustainability, p. 12.
[41] Commission Staff Working Document, Progress report on the assessment and management of combined exposures to multiple chemicals (chemical mixtures) and associated risks, SWD(2020) 250 final, Brussels, 14.10.2020, https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_mixtures.pdf
[42] European Commission, Research and innovation for the European Green Deal, https://research-and-innovation.ec.europa.eu/strategy/strategy-2020-2024/environment-and-climate/european-green-deal_en
[43] Proposal for a Regulation establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC, COM(2022) 142 final, Brussels, 30.3.2022, https://environment.ec.europa.eu/system/files/2022-03/COM_2022_142_1_EN_ACT_part1_v6.pdf
[44] Article 2(28), Proposal for a Regulation establishing a framework for setting ecodesign requirements for sustainable products
[45] Chemicals Strategy for Sustainability, p. 6.
[46] Chemicals Strategy for Sustainability, p. 4.

chemical industry to regain competitiveness by further developing safe and sustainable chemicals and to bring sustainable solutions across sectors."[47] To achieve this objective, a "more coherent, predictable and stronger regulatory framework" would be required. In combination with "nonregulatory incentives," this would "drive the necessary innovation, deliver increased protection, while enhancing the competitiveness of the European chemical industry and its value chains."[48]

The Commission's Recommendation on an assessment framework for 'safe and sustainable by design' chemicals is intended to drive "industry's and public authorities' research and innovation investments in the right direction."[49] A non-exhaustive list of guiding design principles includes a principle entitled "design for end of life," which requires that materials be selected that are "fully biodegradable for uses that unavoidably lead to release into the environment or wastewater."[50] In other words, persistence would be inconsistent with this principle.

2) Chemical safety

In the context of "safe and sustainable," the term "safe" does not mean that a chemical may not pose any risk. As with any other product or activity, "zero risk" is unachievable and not even desirable.[51] Chemical risks must be managed, controlled and reduced to acceptable levels. The REACH Regulation employs the concepts of 'safe use' and imposes chemical safety assessment to reflect this idea.[52]

Under the REACH Regulation, which regulates, but does not ban the production and use of hazardous substances, chemical safety assessment[53] of a hazardous substance is intended to "assess and document that the risks arising from the substance they manufacture or import are adequately controlled during manufacture and use."[54] Risks that are not adequately controlled may be "unacceptable risks" that can trigger the REACH restriction process.[55]

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[47] In this regard, the Commission refers specifically to construction materials, textiles, low-carbon mobility, batteries, wind turbines and renewable energy sources.
[48] Chemicals Strategy for Sustainability, p. 3.
[49] European Commission, Recommendation establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials, C(2022) 8854 final, Brussels, 8.12.2022, https://research-and-innovation.ec.europa.eu/document/download/2c78478d-b493-48c4-9bc9-f97464d22b6f_en
[50] European Commission, Annex to Recommendation establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials, C(2022) 8854 final, Brussels, 8.12.2022, p. 5, https://research-and-innovation.ec.europa.eu/document/download/2c78478d-b493-48c4-9bc9-f97464d22b6f_en
[51] Court of First Instance, Pfizer Animal Health SA, Case T-13/99, 11 Sept. 2002 ("a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified" and "a 'zero risk' does not exist, since it is not possible to prove scientifically that there is no current or future risk associated with" the regulated activities/ products).
[52] See Article 10(a) and 33, REACH Regulation.
[53] Chemical safety assessment must cover (a) human health hazard assessment; (b) physicochemical hazard assessment; (c) environmental hazard assessment; and (d) persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment. Article 14(3), REACH Regulation.
[54] Section 0.1., Annex I, REACH Regulation.
[55] See further Section 3.a.ii, below.

Chemical safety assessment must include "exposure scenarios (where appropriate the use and exposure categories), exposure assessment and risk characterization" for "all identified uses,"[56] and is to be updated when new knowledge of the risks of the substance to human health and/or the environment becomes available.[57] Under REACH, guidance on safe use of a substance (if no chemical safety assessment is required) must include not only information on the classification and labelling of the substance, but also details on safety measures ranging from accidental release measures and exposure controls/personal protection to disposal considerations and information on methods of disposal.[58] To implement this concept, ECHA guidance sets out the principles for carrying out an exposure assessment to determine the conditions of safe use for the uses of a substance, covering exposure for environment, workers and consumers.[59]

3) Conclusions

Thus, the key idea of "safe and sustainable by design" is not that chemicals may not present any risk. Rather, the idea is that regulations would create the incentives that are necessary for the chemical industry to prioritize innovation for substitution of substances of concern by restricting or eliminating the production and use of substances of concern. The emphasis is on bans and restrictions of substances that are deemed to present concerns; pressure on industry to produce 'safe and sustainable by design' substances would do the rest.

This regulatory philosophy, however, requires that substances of concern are correctly identified, and that regulations are targeted specifically at addressing such substances in a manner that eliminates or alleviates the concern. As further discussed below, the PFAS proposal would appear to be at odds with the fundamental prerequisites of the approach required by 'safe and sustainable by design' – it applies a 'shot-gun' approach instead of careful identification of substances of concern and instead of addressing the specific concerns associated with some uses of the targeted substances, it imposes blanket bans on the manufacture, marketing and use thousands of substances, including 'theoretical' substances that have not even been synthesized and may be perfectly non-hazardous and safe.

[56] Article 14(4), REACH Regulation.
[57] Article 22(1)(e), REACH Regulation.
[58] Sections 4 and 5, Annex VI, REACH Regulation.
[59] ECHA, Guidance on Information Requirements and Chemical Safety Assessment, Part D: Framework for exposure assessment, Version 2.0, August 2016, https://echa.europa.eu/documents/10162/17224/information_requirements_part_d_en.pdf/70da6d4b-5acf-40d9-8b75-1e1c311378df?t=1470841898389

2. Main Features of the PFAS Proposal

The proposed PFAS restriction is best appreciated in the context of the features of the evolving EU chemical risk regulation discussed in part 1. The direct legislative background and context, however, is relevant to understanding its legal aspects. Following a brief description of this background, the problematics of the PFAS definition, the grouping and read-across approach, and persistence as harm are explored, including the use of emissions and exposure as proxies for risk. The treatment of thresholds in the PFAS proposal also receives attention. Based on this analysis, the final section of this part presents a precautionary perspective on the proposal.[60] The precautionary approach is illustrative of a broader set of problems that plagues risk regulation[61] and raises specific issues in relation to the large group of substances labelled as PFASs.

a. Policy context

The PFAS proposal had been in the offing for a while. Of course, a specific groups of PFASs substances, such as PFOS and PFOA, are already subject to controls. A few subgroups of PFASs substances have been regulated by the Stockholm Convention on Persistent Organic Pollutants (POPs).[62] These regulations have been implemented by the EU.[63] The Montreal Protocol on Substances that Deplete the Ozone Layer has phased out certain gaseous PFAS substances.[64] In the context of the UNECE Convention on Long-range Transboundary Air Pollution, specific POPs, including some PFAS substances, have also been targeted.[65] In

[60] Cf. L. Bergkamp & J.C. Hanekamp, The draft REACH regime: costs and benefits of precautionary chemical regulation, Environmental Liability 2003, pp. 167-180.
[61] See generally, L. Bergkamp, Understanding the Precautionary Principle, Parts I and II, Environmental Liability, 18–30 and 67–82 (2002). David Vogel, The Politics of Precaution: Regulating Health, Safety, and Environmental Risks in Europe and the United States, Princeton University Press, 2012. Jonathan B. Wiener, Michael D. Rogers, James K. Hammitt, Peter H. Sand, The Reality of Precaution: Comparing Risk Regulation in the United States and Europe, Routledge, 2011. Bergkamp L. Smith, T.T., Legal and Administrative Systems: Implications for Precautionary Regulation, in: The Reality of Precaution, Comparing Risk Regulation in the United States and Europe, RFF Press, Washington, DC - London, pp. 434-479. Bergkamp L., Abelkop A., Chemicals Regulation, in: Emma Lees (ed.), Jorge E. Viñuales (ed.), The Oxford Handbook of Comparative Environmental Law, 2019, Chapter 26.
[62] PFOS and PFOA are subject to restrictions. Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds, and PFOA, its salts and PFOA-related compounds have also been identified for regulation. Stockholm Convention on persistent organic pollutants (POPs), http://www.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx
[63] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants, OJ L 169, 25.6.2019, p. 45–77, as amended. Regulation (EU) 2022/2400 of the European Parliament and of the Council of 23 November 2022 amending Annexes IV and V to Regulation (EU) 2019/1021 on persistent organic pollutants, OJ L 317, 9.12.2022, p. 24–31.
[64] The Montreal Protocol covers substances such as CFCs and HCFCs that are partly or fully halogenated. Montreal Protocol on Substances that Deplete the Ozone Layer, https://ozone.unep.org/treaties/montreal-protocol The EU has implemented the Montreal Protocol through Regulation 1005/2009 of 16 September 2009 on substances that deplete the ozone layer, OJ L 286, 31.10.2009, pp. 1–30, as amended. The EU Regulation goes beyond the Montreal Protocol.
[65] 1998 Aarhus Protocol on Persistent Organic Pollutants (POPs), https://unece.org/environment-policy/air/protocol-persistent-organic-pollutants-pops

addition, the EU regulated certain fluorinated gasses, which have been or are being phased down.[66] Under the REACH Regulation, selected PFASs substances have been subjected to restrictions (e.g., C9-C14 linear and/or branched perfluorocarboxylic acids, C9-C14 PFCAs[67]) or identified as substances of very high concern (SVHCs).[68]

Despite these existing regulations, the proponents of the PFASs restrictions believe that a blanket regulation of all PFASs substances is desirable. The proposal explains that "the very high number of PFASs on the market show that the approach taken until now of regulating them individually (or in small groups of closely related substances) is not efficient and does not fully address the concerns they pose."[69] In addition, the proposal states that widespread use of multiple PFASs substances increases the risk of combined effects. To increase the efficiency of the regulatory efforts and avoid "regrettable substitution," PFASs therefore should be targeted as a group.[70]

Restrictions and bans pursuant to the REACH Regulation are deemed to be the "most effective tool" to address the concerns associated with PFASs substances, since PFASs are used in industrial processes but also in many products. Under the REACH Regulation, the manufacture, placing on the market and uses of PFASs substances can be regulated, banned, or subjected to risk management measures. Both REACH authorization and restriction can provide for derogations, but, unlike under the authorization program, a REACH restriction covers imported products. A restriction is therefore deemed to be the "most appropriate EU-wide instrument to address PFAS concerns at the source."[71]
The proponents failed to explain, however, how their proposal squares with the structure of the existing regulations, which are characterized by a more disciplined approach to grouping, a more rigorous focus on concentration limits, and a less restrictive approach towards exclusions and derogations.[72]

[66] Regulation 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation 842/2006, OJ L 150, 20.5.2014, pp. 195–230.
[67] Entry 68, Annex XVII, REACH Regulation. Perfluorohexane sulfonic acid (PFHxS), its salts and related substances are also being targeted for restrictions under REACH. For an overview, see PFAS Proposal, pp. 64-65.
[68] For an overview, see PFAS Proposal, pp. 64-65.
[69] On this point, the proponents parrot the European Environment Agency: "Due to the large number of PFAS chemicals, a substance-by-substance risk assessment and management approach is not adequate to efficiently prevent risk to the environment and human health from a single PFAS or mixtures of them. Taking precautionary risk management actions for groups of chemicals and promoting the use of chemicals that are 'safe-and-circular-by-design' could help to limit future pollution." European Environment Agency, Emerging chemical risks in Europe — 'PFAS', Copenhagen, December 2019, https://www.eea.europa.eu/publications/emerging-chemical-risks-in-europe
[70] PFAS Proposal, pp. 67-68.
[71] PFAS Proposal, p. 69.
[72] Examples are the restrictions on PFOA (now POPs Regulation), PFOS (now POPs Regulation), TDFAs (entry 73), C9-C14 PFCAs (entry 68), PFHxS (POPs Regulation), PFAS in firefighting foams (proposed), and PFHxA (proposed) set forth in Annex XVII of the REACH Regulation. A number of categories of PFAS substances have been identified as SVHC under the REACH Regulation. See PFAS Proposal, pp. 64-65.

b. Legislative basis

The PFAS proposal would involve bans and restrictions of PFASs pursuant to the REACH Regulation's restrictions regime. This program is viewed as a "safety net" of European chemical regulation.[73] Through a restriction, risks can be managed that are not (or insufficiently) addressed by other REACH procedures. Under the restriction regime, the manufacturing, placing on the market and use of substances presenting unacceptable risks that need to be addressed, can be made subject to total or partial bans or other restrictions following on a science-based assessment of those risks.[74]

i. REACH restriction regime

The core of the restrictions regime, Article 68 of the REACH Regulation provides that "[w]hen there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4) by adopting new restrictions, or amending current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in mixtures or in articles, pursuant to the procedure set out in Articles 69 to 73." Pursuant to this article, "[a]ny such decision shall take into account the socio- economic impact of the restriction, including the availability of alternatives."

Article 69 of the REACH Regulation stipulates that "[i]f the Commission considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, it shall ask the Agency to prepare a dossier which conforms to the requirements of Annex XV." Under the same conditions and requirements, a member state may also propose a restriction. Any such proposal must meet the requirements of Annex XV of the REACH Regulation.

ii. Conditions for restriction of substances

Thus, REACH imposes the following five conditions for the adoption of restrictions:

1. There is "unacceptable risk to human health or the environment" that is "not adequately controlled".
2. This risk arises from the manufacture, use or placing on the market of a substance on its own, in a mixture, or in an article.
3. It needs to be addressed on an EU-wide basis.

[73] Bergkamp L. (editor), The European Union REACH Regulation for Chemicals: Law and Practice, Oxford University Press, 2013, p. 146. ECHA, Guidance for the preparation of an Annex XV dossier for restrictions, June 2007, https://echa.europa.eu/documents/10162/2324906/restriction_en.pdf/d48a00bf-cd8d-4575-8acc-c1bbe9f9c3f6
[74] Recital 23, REACH Regulation.

4. A proposed restriction must take into account the socio- economic impact, including the availability of alternatives.
5. The procedure set forth in the REACH Regulation must be followed.

The first of these criteria, of course, is the key issue in the case of PFASs substances – does the manufacture, use or placing on the market of PFASs substances cause an "unacceptable risk" to human health or the environment that is not adequately controlled? The concept of risk is to be distinguished from the concept of hazard.[75] Whereas hazard refers to an intrinsic property of a substance, the term risk implies exposure to a hazard in the real world, and an assessment of both the chance that harm will occur and the severity of any such harm.[76] Indeed, as discussed below, much of the controversy around the proposed PFAS restriction can be traced back to the standard of unacceptable risk.

iii. Need for EU-wide action

A Union-wide restriction would be needed as the mobility and persistence of PFASs lead to cross-border pollution that cannot be adequately managed by several national regulatory actions. An EU/EEA wide restriction will prevent and reduce the manufacture, placing on the market (including imports), use and release of PFASs within the EU/EEA in a harmonised manner. PFASs and articles containing PFASs produced in one Member State may be transported to and used in other Member States. Even if measures were introduced at Member State level, there is potential for discrepancies in the definitions and scope of any national restrictions (e.g., definition of substances covered, uses covered, concentration thresholds, and transition periods).

According to the proponents of the PFAS restriction, this has implications not only for the degree to which the environment and human health is protected, but also in terms of ensuring the functioning of the internal market. EU-wide action avoids trade and competition distortions, thereby ensuring a level playing field in the internal market as compared to action undertaken by individual Member States. Further, since emitted PFASs substances are transported across borders via air and water, EU-wide measures are the only way to implement controls efficiently and uniformly. In addition, a restriction is able to target imported articles. An EU restriction can serve as a benchmark[77] and result in global action on PFASs and PFAS-containing products.[78]

c. Definition of PFAS

The proposed PFAS restriction employs a very broad definition of PFASs based on chemical structure. PFASs include "per- and polyfluoroalkyl substances (PFASs)" which are defined as "[a]ny substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-

[75] Lofstedt, R. (2011). Risk versus Hazard – How to Regulate in the 21st Century. European Journal of Risk Regulation, 2(2), 149-168. doi:10.1017/S1867299X00001033
[76] Cf. C. J. Leeuwen, J. L. M. Hermens (editors), Risk Assessment of Chemicals: An Introduction, Springer, 1995.
[77] This is known as the "Brussels effect." Anu Bradford, The Brussels Effect: How the European Union Rules the World, Oxford University Press, 2020.
[78] PFAS Proposal, p. 51.

CF2-) carbon atom (without any H/Cl/Br/I attached to it).” There is an exclusion, however, for “[a] substance that only contains the following structural elements: CF3-X or X-CF2-X’, where X = -OR or -NRR’ and X’ = methyl (-CH3), methylene (-CH2-), an aromatic group, a carbonyl group (-C(O)-), -OR’’, -SR’’ or –NR’’R’’’; and where R/R’/R’’/R’’’ is a hydrogen (-H), methyl (-CH3), methylene (-CH2-), an aromatic group or a carbonyl group (-C(O)-).”[79] This exclusion is intended to cover fully degradable PFASs subgroups that only contain some specific structural elements; these substances “do not form ultimately persistent PFAS arrowheads” (degradation products) and can be expected to “ultimately mineralize in the environment.”[80]

The proposal explains that this definition is aligned with the OECD definition of PFASs.[81] The OECD definition “has been scrutinized by the international scientific community and is widely accepted.”[82] This definition is estimated to cover more than 10 000 PFASs, including a few fully degradable PFAS subgroups: “As these fully degradable subgroups, which can be described by their key structural elements, do not fulfil the underlying concern of high persistence, they are excluded from the scope of this restriction proposal.”[83]

PFASs as defined include a variety of substances, “volatile[84] as well as non-volatile PFASs, anionic, cationic, zwitterionic and non-ionic substances, amphoteric liquids (surfactants), etc., with various chain-lengths and degree of fluorination.”[85] Both non-polymeric and polymeric substances are within the scope of the proposed restriction, non-polymeric PFASs include perfluoroalkyl carboxylic acids, perfluorocarbons, perfluoroalkane sulfonic acids and trifluoromethyl substituted substances. Polymeric PFASs include fluoropolymers, perfluoropolyethers and side-chain fluorinated polymers. Fluoro- and other PFAS polymers

[79] PFAS Proposal, p. 4. “In perfluoroalkyl substances all C-H bonds have been replaced by C-F, while in polyfluoroalkyl substances two or more C-H bonds have been replaced by C-F but some C-H bonds still remain in the molecular structure. Polyfluoroalkyl substances containing at least one perfluorinated moiety (-CF2- or -CF3, not being directly attached to -H, -Cl, -Br or -I) are within the definition. For clarification, a perfluorinated olefinic carbon atom (=CF2) or an aromatic ring bound directly to an F-atom (–CF=) does not fulfil the PFAS definition alone (text from OECD (2021). Consequently, olefins and aromatic substances would need additional fluoroalkyl elements to be regarded as PFASs.” PFAS Proposal, p. 18.
[80] PFAS Proposal, p. 9. Mineralize means degrade to CO_2, H_2O and HF.
[81] OECD (2021), Reconciling Terminology of the Universe of Per-and Polyfluoroalkyl Substances: Recommendations and Practical Guidance. OECD Environment, Health and Safety Publications, Series on Risk Management No. 61. Organisation for Economic Co-operation and Development, https://one.oecd.org/document/ENV/CBC/MONO(2021)25/En/pdf The OECD’s Per- and Polyfluoroalkyl Substances (PFAS) project has been funded by the European Union.
[82] PFAS Proposal, p. 2.
[83] PFAS Proposal, p. 2.
[84] “Some substances contain only a single –CF3 group attached to carbon, and because of their structure they are potential precursors to trifluoroacetic acid (TFA). To this subgroup belong, amongst others, some fluorinated gases and active ingredients in biocides, plant protection products and pharmaceuticals containing a -CF3 group bound to an aromatic ring. Fluorinated gases fulfilling the scope definition form the largest contribution by production volume to this subgroup.” PFAS Proposal, p. 19.
[85] PFAS Proposal, p. 14. “A frequently used division is based on alkyl chain length where perfluoroalkyl carboxylic acids (PFCAs) with seven or more perfluorinated carbons and PFSAs with six or more perfluorinated carbons are considered as “long-chain” PFCAs and PFSAs, respectively, and those with shorter perfluoroalkyl chains “short-chain” PFCAs and PFSAs.” PFAS Proposal, p. 18.

are included within the chemical scope although there is little data on these substances[86] and "[g]rouping fluoropolymers with all classes of PFAS for "read across" or structure-activity relationship assessment is not scientifically appropriate."[87] The PFAS proposal sets forth a subdivision of the group of PFASs into many subgroups based on main chemical moieties present.[88]

d. Grouping and read-across

The EU's Chemicals Strategy for Sustainability' (CSS) posited that the grouping of chemicals could be a tool for accelerating the regulation of hazardous substances. Grouping could be employed to "prioritise (…) substances for restrictions for all uses, instead of regulating them one by one." The idea is a "gradual move away from assessing and regulating chemicals substance-by-substance to regulating them by groups." According to the strategy, this move could be achieved by "favouring the assessment by groups of substances with structural or functional similarities."[89] No definition of the proposed grouping methodology has been provided, nor have the rules governing its application been spelled out.

Obviously, the proposed PFAS definition implies the regulation of a large group of diverse chemical substances all at once. The proponents of the PFAS proposal justify the grouping of all PFASs based on the proposition that "all members of the group share a common hazard and risk," which is "the result of the very persistent property of the perfluorinated part(s) of PFAS molecules."[90]

The proponents' reasoning is that specific PFASs substances have been found to be persistent as a result of the PFAS moieties that they contain. This applies to PFASs substances that degrade to PFOA, which is a very persistent substance; it is the common terminal product of the environmental degradation of various PFASs containing the perfluoroheptyl moiety. More generally, the PFAS proposal explains "[o]ver sufficient time

[86] "To date, research has primarily focused on understanding the identity, life cycle, hazard, occurrence and exposure, and risk of non-polymeric PFASs. This has informed development of many risk management measures at the national and international level. To ensure the sound management of the entire class of PFASs, it is equally important to understand polymeric PFASs, which include side-chain fluorinated polymers (SCFPs), fluoropolymers and perfluoropolyethers (Buck et al., 2011; Fiedler et al., 2019)." OECD, Synthesis Report on Understanding Side-Chain Fluorinated Polymers and Their Life Cycle. OECD Series on Risk Management, No. 73, Environment, Health and Safety, Environment Directorate, OECD. Organisation for Economic Co-operation and Development, 2022, https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/synthesis-report-onunderstanding-side-chain-fluorinated-polymers-and-their-life-cycle.pdf
[87] Henry BJ, Carlin JP, Hammerschmidt JA, Buck RC, Buxton LW, Fiedler H, Seed J, Hernandez O. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag. 2018 May; 14(3):316-334. doi: 10.1002/ieam.4035. Epub 2018 Mar 30. PMID: 29424474.
[88] PFAS Proposal, Figure 1, p. 16.
[89] Communication from the European Commission, Chemicals Strategy for Sustainability, COM(2020) 667 final, Brussels, 14.10.2020, https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf ("Chemicals Strategy for Sustainability").
[90] PFAS Proposal, p. 20.

horizons all precursor substances will contribute to environmental stocks of their corresponding arrowhead substances."[91]

The grouping approach employed in the PFAS proposal is claimed to be "a basis for risk assessment also by several scientists, who consider that regulation of PFASs on the basis of persistence alone should already suffice."[92] No further explanation is provided; in particular, it is not clear how this position relates to the requirements for substance restrictions imposed by the REACH Regulation discussed in Section 2.b, above, and 3.a.ii. below.

Further, according to the proponents, the broad grouping approach employed in the PFAS proposal would be justified by the disappointing experience with PFAS regulation since 2014. If PFASs are restricted individually (substance by substance) or per arrowhead group (e.g. PFOA and related substances), they "might be replaced with slightly different non-restricted PFASs (e.g. ADONA or HFPO-DA) with similar risks."[93] On this ground, to avoid regrettable substitution, "all PFASs having equivalent hazard and risk" should be covered in in a single restriction proposal, even though some PFASs included in the scope of the proposed restriction may have a negligible or indeed no current use.[94]

Thus, the broad scope of the PFAS proposal is driven by consideration of environmental and health protection. The grouping approach is based on structural similarity (common perfluoroalkyl moieties). This structural similarity is assumed to present identical or equivalent hazards and risks. These hazards and risks are assumed to arise from the persistent property of the substances due to the constituent compounds and/or the degradation/transformation products. In addition, the grouping has been informed by the desire to avoid regrettable substitution.[95]

Although the proposal relies heavily on some sort of read-across, it is completely silent on this topic. This silence raises an issue as to how the reasoning developed by the proponents compares to the requirements imposed by the REACH Regulation in relation to read-across and grouping.[96]

[91] PFAS Proposal, p. 21.
[92] PFAS Proposal, p. 21. Reference is made to Cousins I.T., DeWitt J.C., Gluge J., Goldenman G., Herzke D., Lohmann R., Ng C.A., Scheringer M., and Wang Z., The high persistence of PFAS is sufficient for their management as a chemical class. Environmental science. Processes & impacts, 2020, 22 (12), 2307-2312. DOI:10.1039/d0em00355g; and Scheringer M., Johansson J.H., Salter M.E., Sha B., and Cousins I.T. , Stories of Global Chemical Pollution: Will We Ever Understand Environmental Persistence?, Environ Sci Technol. 2022, DOI: 10.1021/acs.est.2c06611
[93] PFAS Proposal, p. 21.
[94] These PFASs have been included in the scope because their use may increase as a result of becoming an alternative for other, restricted PFASs or due to new uses.
[95] PFAS Proposal, p. 21.
[96] See for further discussion, Section 3.b.ii, below.

e. Persistence

As discussed, all PFASs substances are deemed to be persistent based on structural similarity. Persistence as such, however, is not a hazard under the EU Regulation on the classification, labeling and packaging of hazardous substances. It is measured in laboratory tests but the relation between such tests and persistence in the environment is unclear.[97] Under the REACH Regulation, a substance that fulfils the persistence, bioaccumulation and toxicity criteria of the pertinent sections of Annex XIII is considered a PBT substance, and a substance that fulfils the criteria for more serious persistence and bioacumulation is regarded as a vPvB substance.[98] The proponents of the PFAS proposal, however, do not suggest that all PFASs substances are either PBT or vPvB substances.

Instead, the PFAS proposal emphasizes persistence, which would be a property of all substances within the scope of the restriction.[99] In this vein, the proposal states explicitly that the "[d]egradation half-lives of the arrowhead PFASs in the environment exceed the criteria for very persistent substances in Annex XIII to REACH by far."[100] Although the proponents refer to other hazardous properties of some PFASs substances,[101] their high persistence is the main concern. To support this proposition, they provide the following reasons:[102]

- "The continuous use and release of these very persistent substances leads to sustained exposure and increasing stocks in the environment."
- "The high persistence in the environment will lead, inevitably, after release to distribution of PFASs from one environmental compartment to another (e.g. from soil to freshwater to marine environment)."

[97] McLachlan, Michael S., Zou, Hongyan, Gouin, Todd, Using Benchmarking To Strengthen the Assessment of Persistence, Environ. Sci. Technol. 2017, 51, 1, 4–11, https://doi.org/10.1021/acs.est.6b03786 ("Current methods for evaluating persistence are based on laboratory tests. The relationship between the laboratory-based estimates and persistence in the environment is often unclear, in which case the current methods for evaluating persistence can be questioned.")

[98] PBT assessment requires that toxicity be established for the substance concerned. Without toxicity, there can be no hazard resulting from PBT classification. vPvB classification requires that substances be both very persistent and very bioaccumulative pursuant to the criteria defined in the REACH Regulation and CLP Regulation.For the identification of PBT substances and vPvB substances "a weight-of-evidence determination using expert judgement" is to be applied. Annex XIII, REACH Regulation ("by comparing all relevant and available information listed in Section 3.2 with the criteria set out in Section 1. This shall be applied in particular where the criteria set out in Section 1 cannot be applied directly to the available information.")

[99] Note that the term "property" in the PFAS proposal is not used in the same meaning of that term in Annex XIII – the very first sentence of this annex states: "This Annex lays down the criteria for the identification of persistent, bioaccumulative and toxic substances (PBT substances), and very persistent and very bioaccumulative substances (vPvB substances) as well as the information that must be considered for the purpose of assessing the P, B, and T properties of a substance." Annex XIII, REACH Regulation.

[100] PFAS Proposal, p. 23.

[101] Figure 4, titled "PFAS properties and property-related concerns resulting from combinations of the properties," lists the following properties: "very high persistence, long-range transport potential, mobility, accumulation in plants, bioaccumulation potential, ecotoxicity, endocrine activity, and effects on human health." PFAS Proposal, p. 23.

[102] PFAS Proposal, p. 24.

- "Even if releases of PFASs are minimised now, PFASs will remain in the environment for a very long time."
- "Furthermore, the combined historic releases of precursor PFASs form arrowhead PFASs over time. Therefore, the precursor stocks in the environment represent a long-term source of arrowhead substances, even if the releases of precursors are stopped."
- "The longer the stock is allowed to increase, the less effective the emission reduction will become."
- "The increasing stock pollution will result in increasing likelihood that known and unknown effects occur, be it by a single chemical and/or in a mixture with other substances."

These reasons presuppose that, in the long term, all PFASs substances pose a risk of causing adverse human health[103] or environmental effects.[104] As additional support for the emphasis on persistence, the proponents reference that persistence is also the core concern of some scientists,[105] and that several of them have suggested to regulate PFASs on the basis of their very high persistence alone, the so-called "P-sufficient approach" for regulatory action.[106] No less than six papers, the proponents note, have opined that persistence is the only or most important property to justify regulation.[107] The proposal does not discuss, however, whether this analysis reflects the weight of the evidence.[108]

[103] With respect to human health effects, the proponents rely on animal and epidemiological studies. See PFAS Proposal, Annex B, which refers, inter alia, to Grandjean P., Timmermann C.A.G., Kruse M., Nielsen F., Vinholt P.J., Boding L., Heilmann C., and Molbak K. (2020): Severity of COVID-19 at elevated exposure to perfluorinated alkylates. Plos One 15 (12). DOI: 10.1371/journal.pone.0244815 The discussion included in this annex, however, includes no critical review of this study and other epidemiological studies. For a discussion of the pitfalls of such studies, see Alvan R. Feinstein, Scientific Standards in Epidemiologic Studies of the Menace of Daily Life, Science 242, 1257-1263 (1988), DOI:10.1126/science.3057627 The proponents admit, however, that "[f]or the vast majority of PFASs, long-term toxicity or carcinogenicity studies as well as epidemiological studies informative on potential carcinogenic effects are not available and thus, human relevance of carcinogenicity of most PFASs is unclear." PFAS Proposal, Annex B, p. 169.

[104] To support this statement, the proponents refer to Bil W., Zeilmaker M., Fragki S., Lijzen J., Verbruggen E., and Bokkers B., Risk Assessment of Per- and Polyfluoroalkyl Substance Mixtures: A Relative Potency Factor Approach. Environmental Toxicology and Chemistry, 2021, 40 (3), 859-870. DOI:10.1002/etc.4835 It is not clear, however, how this paper supports the statement as made.

[105] Specific reference is made to the Helsingør Statement on PFASs and the follow-up Madrid Statement. Scheringer M., Trier X., Cousins I.T., de Voogt P., Fletcher T., Wang Z., and Webster T.F., Helsingor statement on poly- and perfluorinated alkyl substances (PFASs), Chemosphere, 2014, 114, 337-339, DOI:10.1016/j.chemosphere.2014.05.044. Blum A., Balan S.A., Scheringer M., Trier X., Goldenman G., Cousins I.T., Diamond M., Fletcher T., Higgins C., Lindeman A.E., Peaslee G., de Voogt P., Wang Z., and Weber R., The Madrid Statement on Poly- and Perfluoroalkyl Substances (PFASs), Environmental Health Perspectives, 2015, 123 (5), A107-111. DOI: 10.1289/ehp.1509934.

[106] Cf. Cousins I.T., Ng C.A., Wang Z., and Scheringer M., Why is high persistence alone a major cause of concern? Environmental science. Processes & impacts, 2019, 21 (5), 781-792. DOI: 10.1039/c8em00515j. "Persistence alone was the justification for the regulation of PFASs as a class in California." Balan S.A., Mathrani V.C., Guo D.F.M., and Algazi A.M., Regulating PFAS as a Chemical Class under the California Safer Consumer Products Program, Environmental Health Perspectives, 2021, 129 (2). DOI: 10.1289/Ehp7431

[107] PFAS Proposal, p. 24.

[108] The weight of evidence approach involves the "use of a combination of information from several independent sources to give sufficient evidence to fulfil an information requirement." ECHA, Weight of the

f. Emissions and exposure

As discussed, persistence, without more, does not translate into hazard. Likewise, emissions and exposure do not translate into risk, which is a precondition under the REACH Regulation for imposing restrictions. To resolve this issue, the PFAS proposal posits that "PFASs have a high potential for ubiquitous and increasing exposure of the environment," which can lead to "irreversible damage to the environment and humans."[109] It is claimed that "[d]ue to the complex co-occurrence of PFASs in the environment and the very long-term exposures, standard tests do not provide sufficient understanding of possible effects."

Like PBT/vPvB substances,[110] the proponents suggest, PFASs should be treated as non-threshold substances for the purpose of risk assessment. On this basis, any releases can be used as a proxy for risk. Thus, to minimize the risks of PFASs, i.e. the likelihood of adverse effects in the future, any and all releases should be minimized.[111] Because an increasing environmental PFASs stock will result in an increased risk of negative environmental and health impacts and, thus, damages over time, PFASs emissions should be reduced and a restriction will have the desired effect, although "it comes with a delay depending on the persistence of PFASs."[112]

Furthermore, risk assessments on PFASs in the environment require information about physico-chemical and fate properties of PFASs, their persistence under environmental conditions, and any adverse effects associated with their presence in the environment. The proponents admit that "[f]or a large number of chemicals covered by the restriction proposal this information is still incomplete," and "existing information is often uncertain."[113] The absence of reliable information on the PFASs substances covered by the proposal is not regarded as a showstopper for a far-reaching REACH restriction proposal, however. Rather, the proponents of the restriction treat it as a justification for using emissions as a proxy for risk.

In a similar vein, emissions are proposed to be a proxy for the risk reduction capacity of the specific restriction option. The proponents warn, however, that "[w]hile emission estimates

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evidence, available at https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/weight-of-evidence

[109] PFAS Proposal, p. 47.

[110] ECHA has articulated the concerns around PBT/vPvB substances as follows: "Protection of pristine remote areas from PBT/vPvB substances is particularly difficult, as these substances do not degrade near emission sources but may be gradually transported into remote areas. A 'safe' concentration in the environment cannot be established using the methods currently available. A particular concern with vPvB substances is that even if no adverse effects can be demonstrated under laboratory testing conditions, long-term effects might be possible, as high but unpredictable levels may be reached in humans or the environment over extended time periods." ECHA, PBT Assessment, https://echa.europa.eu/understanding-pbt-assessment ECHA, Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB Assessment, June 2017, https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f See also Abelkop A.D.K., Graham J.D., Royer T.V., Persistent, Bioaccumulative and Toxic (PBT) Chemicals: Technical Aspects, Policies, and Practices, CRC Press, 2016.

[111] PFAS Proposal, p. 48.

[112] PFAS Proposal, p. 49.

[113] PFAS Proposal, p. 49.

inform about the pollution flow into the environment, they do not reflect the accumulation of pollution over time due to persistence." Consequently, the use of emission estimates as a proxy for risk "will likely underestimate impacts to be expected, and in particular long-term impacts and damage costs." As discussed further below,[114] there are issues, however, with the "rough and dirty" methodology employed by the proponents to estimate emissions and exposures, and rather than underestimation, overestimation and exaggeration appear to be present.

g. Concentration limits

Not any presence of PFASs substances in substances, mixtures or articles would be prohibited. The proposed restriction sets forth three threshold concentration levels above which the bans will kick in. These concentration limits are:

- 25 ppb for any PFAS as measured with targeted PFAS analysis, with polymeric PFASs being excluded from quantification;
- 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFASs excluded from quantification); and
- 50 ppm for PFASs (polymeric PFASs included); if total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user upon request must provide to the enforcement authorities proof for the fluorine measured as content of either PFASs or non-PFASs.[115]

The proponents explain that the first two values refer to "measurement of PFASs with an available analytical method for a specific set of substances and quantified against reference standards." The third value (50 ppm) applies if targeted analysis is not applicable, e.g. in the case of fluoropolymers. In this case, "as the measured value will also include potential fluorine from sources other than PFASs, it is necessary to differentiate between PFAS and non-PFAS." If total fluorine exceeds 50 mg F/kg, it should be demonstrated that it is non-PFAS-fluorine through either supply chain information or based on analysis.[116]

As a practical matter, these concentration limits will preclude any intentional use of PFASs substances. For this reason, both options for a restriction are billed as bans on PFASs substances.

[114] See section 3.b.iv, below.
[115] PFAS Proposal, p. 4. There are multiple problems associated with measuring and verifying compliance with these limits. The European Committee for Standardization CEN/TC 248, Textile and textile products, WG 26 Test methods for analysis of EC restricted substances, has commented that the proposed restriction "is not logical and clearly defined."
[116] PFAS Proposal, p. 9.

h. Derogations

The PFAS proposal includes two restriction options – a complete ban with derogations and a complete ban without derogations. In the latter case, the transition period would be 18 months. If derogations are provided, these would be use-specific and time-limited; an 18-month transition period plus either a five- or 12-year derogation period.[117] Because cost-related data for a ban of PFASs was scarce and mainly qualitative, the derogations and their duration were based chiefly on the availability and applicability of alternatives to PFASs.

i. Categories of derogations

There are three categories of derogations:

- General derogations that are not limited in time for PFASs used as active substances in plant protection products, biocidal products and human and veterinary medicinal products (MP), which are regulated under specific regulations.
- Use-specific derogations that are time limited (5 or 12 years) for which the proponents deemed the evidence sufficient, of which there are twenty and six that are specific to fluoropolymers and perfluoropolyethers). These derogations would apply to, for example, use of PFASs in textiles used in personal protective equipment and refrigerants in low temperature refrigeration below -50 °C.[118] The derogations for fluoropolymers would apply to uses such as implantable medical devices and fluoropolymer applications in petroleum and mining industry.[119]
- Possible derogations for identified uses for which the evidence base is weak, and which require further substantiation (there are also twenty such possible derogations). These derogations may be confirmed if substantial evidence is provided during the consultation on the restriction proposal.

As the proposal explains, several substances that are used as process agents are derogated from the restrictions. In addition, substances such as chlorofluorocarbon 113 (CFC 113) and hydrochlorofluorocarbon 22 (HCFC 22), which are used as intermediates in the production of fluoropolymers, would not be covered by the proposed restriction, since they do not meet the PFAS definition.[120]

ii. Consulting on derogations

ECHA has structured the public consultation on the PFAS proposal in a way that focuses on informational needs and specifically the derogations. There is a specific checkbox labelled “request for exemption,” and with respect to the proposed derogations, ECHA specifically seeks information on the tonnage of PFAS used per year and the resulting emissions to the

[117] PFAS Proposal, p. 3.
[118] PFAS Proposal, p. 5.
[119] PFAS Proposal, p. 7.
[120] PFAS Proposal, p. 65.

environment for the relevant derogated use.[121] For uses that have not yet been identified, ECHA requests "specific information" on issues such as:

- "[T]he availability, technical and economic feasibility, hazards and risks of alternatives for the relevant use, including information on the extent (in terms of market shares) to which alternative-based products are already offered on the EU market and whether any shortages in the supply of relevant alternatives are expected."
- "For cases in which alternatives are not yet available, information on the status of R&D processes for finding suitable alternatives, including the extent of R&D initiatives in terms of time and/or financial investments, the likelihood of successful completion, the time expected to be required for substitution (including any relevant certification or regulatory approvals) and the major challenges encountered with alternatives which were considered but subsequently disregarded."
- "For cases in which substitution is technically and economically feasible but more time is required to substitute: the type and magnitude of costs (at company level and, if available, at sector level) associated with substitution (e.g. costs for new equipment or changes in operating costs); the time required for completing the substitution process (including any relevant certification or regulatory approvals); information on possible differences in functionality and the consequences for downstream users and consumers (e.g. estimations of expected early replacement needs or expected additional energy consumption); information on the benefits for alternative providers."
- "For cases in which substitution is not technically or economically feasible, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector."

Further, the consultation solicits information on "potential derogations marked for reconsideration," in particular to conduct further assessment of alternatives and socio-economic analysis. As noted above, these "potential derogations for reconsideration after the consultation" involve uses of PFAS where the evidence underlying the assessment of the substitution potential was deemed weak.[122]

[121] ECHA, Comments for Annex XV restriction report Per- and polyfluoroalkyl substances (PFAS), https://comments.echa.europa.eu/comments_cms/AnnexXVRestrictionDossier.aspx?RObjectId=0b0236e1885e69de

[122] "The substitution potential is determined on the basis of i) whether technically and economically feasible alternatives have already been identified or alternative-based products are available on the market at the assumed entry into force of the proposed restriction, ii) whether known alternatives can be implemented before the transition period ends (taking into account time requirements for substitution and certification or regulatory approval), and iii) whether known alternatives are available in sufficient quantities on the market at the assumed entry into force to allow affected companies to substitute. … To strengthen the justifications for a derogation for these uses, additional specific information is requested on alternatives and socio-economic impacts." ECHA, Comments for Annex XV restriction report Per- and polyfluoroalkyl substances (PFAS),

By emphasizing derogations and suggesting that the regulators are open to considering requests for exemptions, ECHA draws the attention away from the fundamentals of the proposed restrictions and the many issues it raises in relation to science, law and policy. These issues are the focus of this paper.[123]

https://comments.echa.europa.eu/comments_cms/AnnexXVRestrictionDossier.aspx?RObjectId=0b0236e1885e69de

[123] ECHA, Comments for Annex XV restriction report Per- and polyfluoroalkyl substances (PFAS), https://comments.echa.europa.eu/comments_cms/AnnexXVRestrictionDossier.aspx?RObjectId=0b0236e1885e69de

3. Problematics of the PFAS Proposal

The previous section described key features of the proposed PFAS restriction, as well as the legislative background and context. It provided a chiefly descriptive analysis intended to enhance general understanding of the scientific, regulatory, and legal aspects of the PFAS proposal. This section builds on that analysis and discusses the proposal's problematics, focusing on those issues arising under the PFAS proposal that raise important questions from a regulatory or legal perspective.

The issues discussed in this section spark key questions in relation to the applicable legal standards, the concept of science-based regulation, and the methodology and reasoning used by the proponents of the PFAS proposal. The concept of "unacceptable risk," which is a critical requirement under the REACH Regulation's restrictions regime, and the proportionality principle are analyzed and applied to the PFAS proposal. Attention is also paid to the restriction of fundamental rights that would result from the proposal.

The methodology and reasoning in the PFAS proposal is first analyzed in general terms, and thereafter related specific issues are reviewed. These issues include the origin, scope, and coherence of the PFAS definition, and the grouping and read-across approach applied by the proponents, the issues of persistence as harm (including the use of emissions and exposure as proxies for risk), and non-threshold substances. Although the proponents do not invoke the precautionary principle, their proposal reflects a strong, even extreme version of the precautionary approach.[124] The relevance of the precautionary approach to the PFAS proposal is analyzed and the consequences for the burden of proof are discussed.

The final part of this section discusses two policy issues associated with the proposed restriction. It focuses on the regulation of perceived, as opposed to actual, risk, and reviews the weighing of the costs and benefits of the PFAS proposal.

a. The Legal Standards

Prior to diving into a detailed analysis of key issues raised by the PFAS proposal, it is useful to review the legal standards that apply to it, since these standards allow us to identify the problematics that need to be addressed. The focus will be on a few legal standards that are particularly important to the proposed restriction.

i. Science-Based Risk Regulation

At the policy level the EU recognizes that its policies should be informed by science. This applies also, or maybe in particular, to the policies enacted pursuant to the Green Deal. The

[124] See further Bergkamp, L., & Kogan, L. (2013). Trade, the Precautionary Principle, and Post-Modern Regulatory Process: Regulatory Convergence in the Transatlantic Trade and Investment Partnership. European Journal of Risk Regulation, 4(4), 493-507. doi:10.1017/S1867299X00003123.

EU not only invests significant amounts in research for the green deal,[125] but has also recognized that science is key to environmental and health regulation. In connection with the toxic-free environment, the Commission has declared that "the regulatory framework will need to rapidly reflect scientific evidence on the risk posed by endocrine disruptors, hazardous chemicals in products including imports, combination effects of different chemicals and very persistent chemicals."[126]

1) EU Treaty

EU laws have always contemplated an important role for science in environmental and health policymaking. The EU Treaty and CLP and REACH Regulations require explicitly that environmental regulation be based on science. The EU Treaty on the Functioning of the European Union (TFEU) instructs the Commission in developing its proposals concerning health, safety, and environmental protection, to take into account "any new development based on scientific facts."[127]

Further, the TFEU stipulates that in preparing its policy on the environment, the EU must "take account of "available scientific and technical data."[128] The proponents of the PFAS Proposal have invoked science to support the restrictions, but they invoke both scientific facts and scientific opinions and have used the available scientific and technical data selectively[129] -- does the PFAS proposal suffer from "citation bias"[130] or "cherry-picking"[131]?

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[125] JRC, Science for the European Green Deal, https://joint-research-centre.ec.europa.eu/jrc-science-and-knowledge-activities/science-european-green-deal_en

[126] European Commission, Communication on 'The European Green Deal,' COM(2019) 640 final, Brussels, 11.12.2019, https://eur-lex.europa.eu/resource.html?uri=cellar:b828d165-1c22-11ea-8c1f-01aa75ed71a1.0002.02/DOC_1&format=PDF

[127] Article 114(3), TFEU. "Within their respective powers, the European Parliament and the Council will also seek to achieve this objective."

[128] Article 191(3) TFEU. "[T]he economic and social development of the Union as a whole and the balanced development of its regions" must also be taken into account."

[129] It is not clear, for instance, whether and, if so, how, all data that is available in the REACH registrations dossiers for the PFAS substances covered by the proposal have been adequately considered. This applies in particular to those substances that have not been classified for any hazard.

[130] Duyx, B., Urlings, M., Swaen, G., Bouter, L., & Zeegers, M., Citation bias: questionable research practice or scientific misconduct? Journal of the Royal Society of Medicine, 2022, 115(4), 124-124, [01410768221084080]. https://doi.org/10.1177/01410768221084080 Urlings, M. J. E., Duyx, B., Swaen, G. M. H., Bouter, L. M., & Zeegers, M.P., Citation bias and other determinants of citation in biomedical research: findings from six citation networks. Journal of Clinical Epidemiology, 2021, 132, 71-78, https://doi.org/10.1016/j.jclinepi.2020.11.019 Duyx, B., Standing on one shoulder: citation bias in the epidemiological literature. Doctoral Thesis, Maastricht University, 2019, https://doi.org/10.26481/dis.20190417bd Duyx, B., Urlings, M. J. E., Swaen, G. M. H., Bouter, L. M., & Zeegers, M. P. (2017). Scientific citations favor positive results: a systematic review and meta-analysis. Journal of Clinical Epidemiology, 88, 92-101. https://doi.org/10.1016/j.jclinepi.2017.06.002 Duyx, B.; Urlings, M.J.E.; Swaen, G.; Bouter, L.M.; Zeegers, M.P., Systematic Review of Citation Bias, https://doi.org/10.34894/0TNI44, DataverseNL, V4

[131] Janice M. Morse, "Cherry Picking": Writing From Thin Data, Qualitative Health Research, 2010, Vol.20, Issue 1, p. 3, https://journals.sagepub.com/doi/epdf/10.1177/1049732309354285. Moti Mizrahi (2015) Historical Inductions: New Cherries, Same Old Cherry-picking, International Studies in the Philosophy of Science, 29:2, 129-148, DOI: 10.1080/02698595.2015.1119413 Evan Mayo-Wilson, Tianjing Li, Nicole Fusco, Lorenzo Bertizzolo, Joseph K. Canner, Terrie Cowley, Peter Doshi, Jeffrey Ehmsen, Gillian Gresham, Nan Guo, Jennifer A.

Cherry-picking does not result in a balanced overview of the entire literature on PFAS with a clear identification of data gaps and uncertainties; that is not to suggest that the proponents of the PFAS proposal ignore uncertainties, but rather that even where they discuss uncertainties, their analysis and conclusions are rather one-sided.[132] As discussed further below, the PFAS proposal reflects a concept of science and science-based regulation that goes beyond the original meaning of these terms; for instance, the proposal employs precautionary generalizations and extrapolates from a few data points to a large number of substances based on assumptions.

2) EU chemical legislation

The idea of science-based regulation is deeply embedded in the EU's chemical regulations. Under the CLP Regulation, information may be used for purposes of identifying hazards and classifying substances and mixtures if it is "adequate, reliable and scientifically valid for the purpose of the evaluation."[133] Any tests for purposes of classification must be conducted in accordance with "sound scientific principles that are internationally recognized."[134] Similar requirements are set forth in other provisions of the CLP Regulation. Likewise, the REACH Regulation stipulates that ECHA "should be central to ensuring that chemicals legislation and the decision-making processes and scientific basis underlying it have credibility with all stakeholders and the public."[135] Numerous other provisions of REACH confirm that decision-making pursuant to its various regulatory regimes must be science- based.[136]

ECHA has recognized the importance of this mandate and is committed to objective, science-based decision-making. Its core values include "trustworthiness," which requires that its "decisions are science based, consistent and impartial."[137] ECHA's Code of Good Administrative Behavior, which binds the agency, provides that "when taking decisions, the staff shall take into consideration the relevant factors and give each of them its proper

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Haythornthwaite, James Heyward, Hwanhee Hong, Diana Pham, Jennifer L. Payne, Lori Rosman, Elizabeth A. Stuart, Catalina Suarez-Cuervo, Elizabeth Tolbert, Claire Twose, Swaroop Vedula, Kay Dickersin, Cherry-picking by trialists and meta-analysts can drive conclusions about intervention efficacy, Journal of Clinical Epidemiology, Volume 91, 2017, pp. 95-110, https://doi.org/10.1016/j.jclinepi.2017.07.014 Kevin R. Murphy & Herman Aguinis, HARKing: How Badly Can Cherry-Picking and Question Trolling Produce Bias in Published Results?, Journal of Business and Psychology (2019) 34:1–17, https://doi.org/10.1007/s10869-017-9524-7

[132] For further discussion, see Section 3, below.

[133] Article 5(2) and 6(2), CLP Regulation.

[134] Article 8(3)(b), CLP Regulation.

[135] Recital 95, REACH Regulation ("it is vital to ensure its independence, high scientific, technical and regulatory capacities, as well as transparency and efficiency").

[136] Recital 104, for instance, states that "[i]t is necessary to ensure close cooperation between the Agency and the competent authorities working within the Member States so that the scientific opinions of the Committee for Risk Assessment and the Committee for Socio-economic Analysis are based on the broadest possible scientific and technical expertise appropriate which is available within the Community." The term "full study report," which is the evidence used under REACH, is defined as "a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed." Article 3(27), REACH Regulation.

[137] ECHA, Values, https://echa.europa.eu/about-us/who-we-are/values

weight in the decision, whilst excluding any irrelevant element from consideration."[138] In its communication on the chemicals strategy, the Commission has confirmed the commitment to "evidence-based policy making."[139]

3) Lack of scientific basis of PFAS proposal

These high standards apply also to the PFAS proposal. A REACH restriction must be science-based, which means that the PFAS proposal should be adequately supported by scientific evidence. As the REACH Regulation stipulates, an Annex XV dossier for a proposed restriction must consider "the information on the substance contained in the technical dossier and on other available and relevant information," including "[a]vailable information from assessments carried out under other international and national programmes."[140] The information to be considered includes "information related to the hazards of the substance, the exposure arising from the manufacture or import, the identified uses of the substance, operational conditions and risk management measures applied or recommended to downstream users to be taken into account." If a manufacturer or importer considers that the chemical safety assessment carried out for one substance is sufficient to assess and document that the risks arising from another substance or from a group or 'category' of substances are adequately controlled, it may use the chemical safety assessment for the other substance or group or 'category' of substances, if a justification is given.[141]

In light of these requirements, the PFAS proposal's scientific validity raises issues.[142] The question should be asked whether the grouping approach and the implicit "read-across" strategy employed by the proponents is based on adequate scientific data and complies with the criteria for read-across justifications set forth in the REACH Regulation.[143] For REACH registrants, ECHA has required that a read-across-approach must fall "within the conditions for using grouping and read-across approaches set out in Annex XI, section 1.5 of the REACH Regulation."[144] The use of persistence as proxy for hazard, and emissions as a proxy for exposure to hazard, and, thus, risk, raises questions as to whether these steps are scientifically valid for the broad group of substances covered by the proposal.

The proponents refer to regulatory assessments conducted elsewhere in the world to support the proposed restriction. A balanced approach to policymaking requires, however, that not only those assessments that support the proposed policy, but also any assessments that do not support the policy are identified and discussed. It is not clear how regulatory science-based assessments relevant to PFAS conducted worldwide have been taken into

[138] Article 9, Objectivity, ECHA Code of Good Administrative Behavior, https://echa.europa.eu/documents/10162/17203/code_of_good_administrative_behaviour_en.pdf
[139] Chemicals Strategy for Sustainability, p. 4.
[140] Section 0.5, Annex I, REACH Regulation (Annex XV refers to Annex I). "Deviations from such assessments shall be justified."
[141] Section 0.4., Annex I, REACH Regulation.
[142] See generally, Schrefler, L., & Pelkmans, J. (2014). Better Use of Science for Better EU Regulation. European Journal of Risk Regulation, 5(3), 314-323. doi:10.1017/S1867299X00003846
[143] Article 13(1) and Section 1.5, Annex XI, REACH Regulation.
[144] ECHA, Grouping of substances and read-across, https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

account; the proposal merely refers selectively to conclusions that are believed to support a broad restriction.

Further, the PFAS proposal does not indicate whether the key studies on which they rely to support their proposal have been reviewed by experts in the field to determine study quality, reliability and relevance for the purpose for which they use it. Not all data and studies on which the PFAS proposal is based have been made available for public scrutiny, and no robust study summaries have been released for each of the key studies, which limits the ability to verify and reproduce the analysis set forth in the proposal. Although the REACH Regulation requires that "[f]or hazard information which has not been previously submitted to the Agency, a robust study summary shall be included in the dossier," [145] no such summaries are included in the PFAS dossier. It does not appear that the proponents had the key studies on which they rely to support their proposal reviewed by experts to determine the study quality and reliability for the purpose for which they use it. And although science-based risk assessment is the cornerstone of EU chemical risk regulation,[146] no risk assessment is available for the vast majority of the substances covered by the PFAS proposal.

While this may not be deemed conclusive proof that the PFAS proposal is scientifically invalid, the discrepancies between the information requirements and the dossier as submitted raise a series of questions around the methodology that has been employed to compile the proposal, the consistency of the reasoning employed by the proponents with the legal requirements and rules, and, indeed, the extent to which relevant science supports the wide-ranging analysis and conclusions reached.[147] These issues are explored in more detail in subsequent sections.

ii. 'Unacceptable risk'

In Section 2.b, above, the conditions under which REACH restrictions may be imposed have been discussed. The core condition is that an "unacceptable risk to human health or the environment that is not adequately controlled" be present. This risk must arise from "the manufacture, use or placing on the market of substances" and it "needs to be addressed on a Community-wide basis."[148] Here, the focus is on the "unacceptable risk" condition; the other two conditions are not discussed any further.

[145] Section I. Introduction, Annex XV, REACH Regulation.
[146] The REACH Regulation established within ECHA a Committee for Risk Assessment (RAC), which prepares opinions on risks of substances to human health and the environment in connection with REACH and CLP processes. Cf. European Commission, Better regulation toolbox, Chapter 2 – How to carry out an impact assessment, https://commission.europa.eu/system/files/2022-06/br_toolbox_-_nov_2021_-_chapter_2.pdf
[147] Cf. Lucas Bergkamp, The Reality of Risk Regulation, European Journal of Risk Regulation, 8 (2017), pp. 56–63 ("With media hypes and scares dominating the risk regulatory arena, "hyped", but relatively insignificant risks may draw regulators' attention and resources away from more significant risks.")
[148] The REACH system, however, contemplates that some substances posing risks that are not adequately controlled, will not be subjected to restrictions: there must also be a need to address the risks 'on a Community-wide basis'. ECHA suggests that this condition is not met if better enforcement of existing legislation is sufficient to address the risk. ECHA, Guidance for the preparation of an Annex XV dossier for

1) The meaning of unacceptable risk

The concept of 'unacceptable risk'[149] is not defined in the REACH Regulation, nor does the REACH Regulation explain how the term 'unacceptable risk' relates to 'adequate control'.[150] The provisions regarding the adoption of restrictions could be interpreted to suggest that 'unacceptable risk' is the flip side of 'adequate control'. Under the restrictions procedure, the Commission must instruct ECHA to prepare a dossier in accordance with REACH, Annex XV (a restrictions proposal), if it finds that a substance 'poses a risk to human health or the environment that is not adequately controlled' and 'needs to be addressed'.[151] ECHA's proposal for restrictions must describe a substance's risks in accordance with the rules for the CSR, which focus on 'adequate control'.[152]

According to ECHA Guidance, the term 'unacceptable risk' covers both situations where risks are not adequately controlled and situations where the risks of each of several individual substances are adequately controlled, but the aggregated exposure would create an unacceptable risk.[153] This last situation involves synergistic, cocktail or combined effects of multiple substances, and is deemed to be relevant to PFASs substances.

2) Unacceptable risk in the PFAS proposal

The PFAS proposal treats the condition of "unacceptable risk" in a cavalier manner. The proponents note first that "due to the non-threshold nature of the hazards, the risks cannot be quantified, and current releases of PFASs should be minimised." As any release of PFAS should be considered a proxy for risk, due to the ongoing releases, the risks associated with PFAS would currently not be adequately controlled. In a rather conclusory statement, the proponent then argue that "[b]ased on this unacceptable risk for human health and/or the environment identified for the group of PFASs, measures are needed to minimize the releases to the environment and reduce human exposure to a minimum."[154] In the summary section, the proponents conclude that "PFASs should be treated as non-threshold

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restrictions, June 2007, https://echa.europa.eu/documents/10162/2324906/restriction_en.pdf/d48a00bf-cd8d-4575-8acc-c1bbe9f9c3f6

[149] Risk is not defined either, but it is clear from the structure of the REACH Regulation that risk means hazard plus exposure. Put differently, risk is the likelihood that harm from a specific hazard will occur at some magnitude at some point in time. "Risk encompasses impacts on public health and on the environment and arises from exposure and hazard." C.J. van Leeuwen, T.G. Vermeire (editors), Risk Assessment of Chemicals: An Introduction, Springer, second edition, 2007. Cf. Lofstedt, R. (2011). Risk versus Hazard – How to Regulate in the 21st Century. European Journal of Risk Regulation, 2(2), 149-168. doi:10.1017/S1867299X00001033

[150] For a discussion of the term 'acceptable risk' in the context of product liability, see Bergkamp, L. (2015). Is There a Defect in the European Court's Defect Test? Musings about Acceptable Risk. European Journal of Risk Regulation, 6(2), 309-322. doi:10.1017/S1867299X00004633

[151] Article 69(1), REACH Regulation. Zander, J. (2011). Risk versus Hazard before the EU Courts – A Comment. European Journal of Risk Regulation, 2(2), 205-208. doi:10.1017/S1867299X00001148

[152] Annex XV, REACH Regulation.

[153] ECHA, Guidance for the preparation of an Annex XV dossier for restrictions, June 2007, p. 14, https://echa.europa.eu/documents/10162/2324906/restriction_en.pdf/d48a00bf-cd8d-4575-8acc-c1bbe9f9c3f6

[154] PFAS Proposal, p. 50.

substances for the purpose of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment and environmental monitoring data regarded as a proxy for an unacceptable risk." Because the proposed restriction "enables a regulatory path to prevent the increase of general PFAS exposures,"[155] it is deemed to meet the unacceptable risk condition imposed by the REACH Regulation.

The legal standard of "unacceptable risk," however, requires more than a theoretical argument. As a general rule, policymakers must ensure that "as thorough a scientific evaluation of the risks as possible" is conducted so that, "[n]otwithstanding the existing scientific uncertainty, the scientific risk assessment" enable them "to ascertain, based on the best available scientific data[156] and the most recent results of international research, whether matters have gone beyond the level of risk that it deems acceptable for society."[157]

3) Hazard and risk

The dossier that is to be prepared pursuant to Annex XV (which refers to Annex I) must "describe in detail why and on the basis of which information" any hazard associated with a substance will result in unacceptable risk.[158] This dossier's purpose is to provide the policymaker with "the necessary scientific information to enable it to determine, in full knowledge of the facts, whether or not there is an unacceptable risk to health and the environment."[159]

Hypothetical exposure to a potential hazard, whether current or future, without adequate scientific evidence of the effects on human health or the environment due to intrinsic hazardous properties of a substance, does not amount to "unacceptable risk" under *Article 68 REACH*.[160] More generally, the European courts have rejected "mere conjecture" as a foundation of a preventive measure.[161] The proponents' assertion that "all PFASs and/or their degradation products" are persistent[162] is no more than mere conjecture.

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[155] PFAS Proposal, p. 190.
[156] Cf. Hanekamp, J., & Bergkamp, L. (2016). The 'Best Available Science' and the Paris Agreement on Climate Change. European Journal of Risk Regulation, 7(1), 42-48. doi:10.1017/S1867299X00005365
[157] Pfizer Animal Health SA v Council of the European Union, Case T-13/99, Judgment of the Court of First Instance, 11 September 2002, para. 162, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:61999TJ0013 ; Cf. International Cadmium Association (ICdA) and Others v European Commission, Case T-456/11, Judgment of the General Court, 14 November 2013, para. 52, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62011TJ0456
[158] Global Silicones Council and Others v European Commission, Case T-226/18, 30 June 2021, para. 339, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62018TJ0226
[159] Global Silicones Council and Others v European Commission, Case T-226/18, 30 June 2021, para. 217, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62018TJ0226
[160] Cf. European Commission v Éditions Odile Jacob SAS, Case C-404/10 P, Judgment of the Court, 28 June 2012, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62010CJ0404
[161] Court of First Instance, Pfizer Animal Health SA, Case T-13/99, 11 Sept. 2002 ("a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified" and "a 'zero risk' does not exist, since it is not possible to prove scientifically that there is no current or future risk associated with" the regulated activities/ products).
[162] See, e.g., PFAS Proposal, p. 1. They reinforce the conjecture with the following statements: "With the constantly increasing concentrations of PFASs in the environment due to their persistence and ongoing

4) Lack of probable serious effects

The lack of any evidence of "unacceptable risk" (or "probable serious effects to human health or the environment" equivalent to the hazards/risks covered by the REACH Regulation,[163] if such effects amount to an "unacceptable risk") is even more problematic in the case of the proposed PFAS ban since there is no information whatsoever on the vast majority of PFAS substances included in group of substances that would be subjected to restrictions. To justify a REACH restriction, the authorities must demonstrate, on the basis of the available scientific evidence, that there is a risk that should be regarded as unacceptable, with respect to each substance to be restricted. The proponents may have such evidence for some of the PFAS substances they intend to ban, but for the bulk of the ten thousand substances that would be phased out, they stand empty-handed – even worse, had they looked, they would have found scientific data that contradict their hypothesis. Consequently, the proposal fails to meet the legal requirements imposed by the REACH Regulation.[164]

5) Equivalent concern?

In addition, the proponents of the broad ban explain that they have chosen to include all PFASs "having equivalent hazard and risk in a single restriction proposal, to avoid regrettable substitution by other PFASs."[165] This explanation raises more questions than it answers, however. Insofar as the proponents intend to rely on the concept of an "equivalent level of concern" set forth in the REACH Regulation,[166] this concept is included in a provision that applies only to the authorization regime, not to restrictions, which are subject to the "unacceptable risk" standard. Incidentally, the fact that the proponents had to resort to a concept of the authorization regime, suggests also that they have chosen the wrong regulatory option and should have pursued listing of PFAS for authorization instead of a broad restriction.[167]

Even if the "equivalent concern" concept could, by analogy, be applied to restrictions, the dossier submitted by the proponents asserts, but does not prove, that the bulk of PFAS substances subject to it raise any such concern. Accordingly, the proposal fails to meet the standard consistently applied by the European courts, pursuant to which it must be "established, on a case-by-case basis, on the basis of scientific evidence, on the one hand, that it is probable that the substances concerned have serious effects on human health or

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emissions, the exposure of humans and the environment to these substances will inevitably lead to negative effects. Also, exposure to PFASs has a high potential for intergenerational effects."

[163] See Article 57, REACH Regulation.

[164] See also Section 3.a.iv, below.

[165] PFAS Proposal, p. 21.

[166] Article 57(f), REACH Regulation.

[167] Annex XIV of the REACH Regulation sets forth substances subject to the authorization regime. For a comparison of REACH authorization to REACH restriction, see Bergkamp L. & Herbatschek N., Regulating Chemical Substances under REACH: The Choice Between Authorization and Restriction and the Case of Dipolar Aprotic Solvents, Review of European Community and International Environmental Law, 2014, pp. 221-245.

the environment, and, on the other, that those effects 'give rise to an equivalent level of concern to those of [CMR, PBT or vPvB substances]'."[168] These two conditions are cumulative, "with the result that the identification of a substance as being of very high concern must be rejected if either of those conditions is not met."[169] The PFAS proposal meets neither of these two conditions.

Given the court's emphasis on "case-by-case basis" and "on the basis of scientific evidence," the PFAS proposal would appear to be off the mark. Rather than providing scientific evidence on a case-by-case basis for each of the substances subject to the restriction, the proponents paint with a broad brush and merely impute hazard and risk to the majority of the substances covered by it.[170] In this manner, no "unacceptable risk" can be established for these substances – imputing risks to substances is unacceptable.

6) Substances of very high concern?

Under the rules relating to the identification of a substance as substance of very high concern (SVHC), the proposal would also fail. Indeed, the REACH Regulation requires explicitly that there is "scientific evidence of probable serious effects to human health or the environment" for a specific substance.[171] Likewise, as a prerequisite for regulation, an Annex XV dossier must include "the identity of substance(s) concerned and whether it is proposed to be identified as a CMR according to Article 57(a), (b) or (c), a PBT according to Article

[168] Chemours Netherlands v ECHA, Case T-636/19, Judgment of the General Court, 23 February 2022, https://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=T-636/19; BASF Grenzach GmbH v European Chemicals Agency, Case T-125/17, Judgment of the General Court, 20 September 2019, https://curia.europa.eu/juris/document/document.jsf?docid=222102&doclang=EN ; Fédération des entreprises du commerce et de la distribution (FCD) and Fédération des magasins de bricolage et de l'aménagement de la maison (FMB) v Ministre de l'écologie, du développement durable et de l'énergie, Case C-106/14, Judgment of the Court, 10 September 2015, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62014CJ0106

[169] Hitachi Chemical Europe and Polynt v ECHA, C-324/15 P, judgment of 15 March 2017, EU:C:2017:208, paragraph 26. The Court added: "Article 57(f) of Regulation No 1907/2006 therefore requires that the effects of the substance on human health or the environment be capable of being regarded as 'serious', on account of, for example, their significance or their irreversible nature. The examination of that condition is based on an assessment of the hazards to human health or to the environment, on the basis of the information in the relevant parts of Sections 1 to 4 of Annex I to Regulation No 1907/2006, as stated in Section 2 of Annex XV to that regulation. It is therefore clear that Article 57(f) of that regulation requires an analysis of the hazards arising from the intrinsic properties of the substance under consideration." Id, paragraph 27.

[170] See further Section 3.b.ii, below.

[171] These serious effects should be equivalent to those referenced in Articles 57(a) to (e) REACH. See also e.g., Chemours Netherlands v ECHA, Case T-636/19, Judgment of the General Court, 23 February 2022, https://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=T-636/19; BASF Grenzach GmbH v European Chemicals Agency, Case T-125/17, Judgment of the General Court, 20 September 2019, https://curia.europa.eu/juris/document/document.jsf?docid=222102&doclang=EN ; *Fédération des entreprises du commerce et de la distribution (FCD) and Fédération des magasins de bricolage et de l'aménagement de la maison (FMB) v Ministre de l'écologie, du développement durable et de l'énergie,* Case C-106/14, Judgment of the Court, 10 September 2015, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62014CJ0106

57(d), a vPvB according to Article 57(e), or a substance of equivalent concern according to Article 57(f)."[172]

In light of the similarity of the REACH restrictions and authorization regimes, and the fact that the choice for a restriction of PFAS is justified by practical considerations (i.e., chiefly the applicability to imports[173]), the term "unacceptable risk" should be deemed not to set a lower standard than the standard of probable serious effects, which are to be proven by scientific evidence for the substance concerned.[174]

7) Persistence as unacceptable risk?

Given that PFASs substances are proposed to be restricted based on their persistence, the question arises whether the concept of "unacceptable risk" should be interpreted differently with respect to persistent, bioaccumulative and toxic substances (PBT substances), and very persistent and very bioaccumulative substances (vPvB substances). The REACH Regulation is crystal clear that persistence is insufficient for a substance to be identified as PBT or vPvB – in addition to persistence, bioaccumulation and/or toxicity is required.[175] Judgments of the European courts have confirmed that persistence alone is not enough. As the court put in one case:

> "[T]he legislature requires a substance to be both persistent and bioaccumulative, where its toxicity is proved, or very persistent and very bioaccumulative to be identified as a substance of very high concern. The legislature does not allow a substance to be identified on the grounds that it is persistent and mobile but not bioaccumulative. Mobility is not of the same level of concern as bioaccumulation. ECHA's guidance states that the potential to contaminate remote areas can only occur if a substance is both persistent and bioaccumulative, besides being potentially toxic. Persistence – in conjunction with other effects that are insufficient in themselves – is not sufficient as such to identify a substance as of very high concern."[176]

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[172] Section 2, Annex XV, REACH Regulation. By way of justification, a restriction proposal must also include a "comparison of the available information with the criteria in Annex XIII for PBT according to Article 57(d), and vPvBs according to Article 57(e), or an assessment of the hazards and a comparison with Article 57(f), according to the relevant parts of Sections 1 to 4 of Annex I shall be completed. This shall be documented in the format set out in Part B of the Chemical Safety Report in Annex I." This kind of justification is missing for the vast majority of substances targeted by the PFAS proposal.

[173] PFAS proposal, p. 2 ("A restriction can cover a wide range of uses and can address the risks arising from the manufacture and use of the substances as such as well as in other substances, in mixtures and in articles, including imported articles from outside the EU. Hence, a restriction is the most appropriate and effective option to adequately control such a large and complex group of substances which are used in numerous applications.")

[174] Cf. L. Bergkamp & N. Herbatschek, Regulating Chemical Substances under REACH: The Choice Between Authorization and Restriction and the Case of Dipolar Aprotic Solvents, Review of European Community and International Environmental Law, 2014, pp. 221-245.

[175] See further Section 3.b.iii, below.

[176] Chemours Netherlands v ECHA, Case T-636/19, Judgment of the General Court, 23 February 2022, https://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=T-636/19, para. 88. See also BASF Grenzach GmbH v European Chemicals Agency, Case T-125/17, Judgment of the General Court, 20 September 2019,

Thus, there is no reason to believe that the concept of "unacceptable risk" would encompass risk arising from mere persistence, which is not a hazard under the EU chemical legislation.[177] At the very least, a PBT or vPvB classification would be necessary before a risk caused by a substance's persistence could rise to the level of an unacceptable risk.[178]

Further, pursuant to Annex XIII of the REACH Regulation, which specifies "the information that must be considered for the purpose of assessing the P, B, and T properties of a substance," a weight-of-evidence (WoE) determination[179] based on expert judgement is to be applied.[180] This WoE determination must consider "all relevant and available information" on a series of points listed, such as degradation in surface water, soil and sediment, as well as other information "provided that its suitability and reliability can be reasonably demonstrated."[181] No such WoE determination is available for most, if not all, substances to be covered by the proposed ban.

iii. Risk assessment

A risk assessment does not necessarily have to be entirely quantitative.[182] The general rule is that a risk assessment should be quantitative where possible. Quantification is also required

https://curia.europa.eu/juris/document/document.jsf?docid=222102&doclang=EN ; Fédération des entreprises du commerce et de la distribution (FCD) and Fédération des magasins de bricolage et de l'aménagement de la maison (FMB) v Ministre de l'écologie, du développement durable et de l'énergie, Case C-106/14, Judgment of the Court, 10 September 2015, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62014CJ0106

[177] The Court of Justice has recognized that mobility may play a role in exposure assessment, however, since for a mobile substance "there are no local or intermittent sinks for the pollution stock and therefore the substance has high potential to cause continuous increase of exposure of wildlife to that substance." Chemours Netherlands v ECHA, Case T-636/19, Judgment of the General Court, 23 February 2022, para. 196, https://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=T-636/19. For many PFAS, however, there is no evidence of such mobility.

[178] Note, too, that the standards for authorization and derogations from restriction are fundamentally different: authorizations, under the adequate control route, can be granted if risks are not unacceptable, but the basis for derogations under restrictions can only be socio-economic, since unacceptable risk has already been established. Thus, a derogation is not equal to an authorization.

[179] "A weight-of-evidence determination means that all available information bearing on the identification of a PBT or a vPvB substance is considered together, such as the results of monitoring and modelling, suitable in vitro tests, relevant animal data, information from the application of the category approach (grouping, read-across), (Q)SAR results, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well documented case reports and observations. The quality and consistency of the data shall be given appropriate weight. The available results regardless of their individual conclusions shall be assembled together in a single weight-of-evidence determination. The information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions. The identification shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products." Introduction, Annex XIII, REACH Regulation.

[180] Introduction, Annex XIII, REACH Regulation.

[181] Section 3.2, Annex XIII, REACH Regulation.

[182] But see Opinion AG Bot, Case C-15/10, Étimine SA v Secretary of State for Work and Pensions, 24 March 2011. Risk assessment is defined as "the likelihood that one of the hazards associated with a substance will occur as a result of human or environmental exposure to that substance." Therefore, "classification and labelling based on risk are linked to specific use and specific conditions of exposure."

by the requirement imposed by the European courts[183] and the Commission[184] that a scientific evaluation of risks be "as thorough a as possible". In some cases, however, the REACH Regulation accommodates qualitative risk assessments.

1) Qualitative risk assessment

In this vein, a qualitative risk assessment is permitted for substances that do not have a DNEL or a PNEC threshold.[185] If a DNEL or PNEC has been established for a substance, qualitative risk assessment is not permitted, not even where combined exposure might be surmised.[186] On the other hand, "for those human effects and those environmental spheres for which it was not possible to determine a DNEL or a PNEC, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario" is to be carried out.[187] Specifically with respect to PBT and vPvB substances, the manufacturer or importer is required to ensure that the exposure estimations are reflected in scenarios and recommended risk management measures aimed at minimizing exposures and emissions to humans and the environment throughout the lifecycle of the substance.

In some cases, a risk assessment conducted on one substance may also be used for another substance. This is the case where the physicochemical, toxicological and eco-toxicological properties of the substances concerned are likely to be similar (or follow a regular pattern) as a result of structural similarity. Such substances may be considered a group, or category.[188] The issues in relation to the grouping approach employed in the PFAS proposal are discussed further below.

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[183] Pfizer Animal Health SA v Council of the European Union, Case T-13/99, Judgment of the Court of First Instance, 11 September 2002, para. 162, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:61999TJ0013 ; Cf. International Cadmium Association (ICdA) and Others v European Commission, Case T-456/11, Judgment of the General Court, 14 November 2013, para. 52, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62011TJ0456

[184] "Risk evaluations include a series of factors to be taken into account to ensure that they are as thorough as possible." European Commission, Communication on the Precautionary Principle, COM(2000) 1 final , Brussels, 2.2.2000, https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:en:PDF

[185] Section 6.5, Annex I, REACH Regulation.

[186] For a case involving the intended release of substances from wash-off personal care products, see Global Silicones Council and Others v Commission, Case T-226/18, para. 194-196, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62018TJ0226

[187] Section 6.5, Annex I, REACH Regulation.

[188] "If the manufacturer or importer considers that the chemical safety assessment carried out for one substance is sufficient to assess and document that the risks arising from another substance or from a group or 'category' of substances are adequately controlled then he can use that chemical safety assessment for the other substance or group or 'category' of substances. The manufacturer or importer shall provide a justification for this." Section 0.4, Annex I, REACH Regulation. "The term category approach is used when read-across is employed between several substances that have structural similarity." ECHA's Read-Across Assessment Framework (RAAF), March 2017, https://echa.europa.eu/documents/10162/13628/raaf_en.pdf/614e5d61-891d-4154-8a47-87efebd1851a, p. 7.

2) Case-by-case risk assessment

Even where the REACH Regulation accommodates qualitative risk assessment, such assessment, like quantitative risk assessment, must otherwise be conducted in accordance with the applicable legal standards, in particular those laid down in Annexes I and XV REACH Regulation.[189] Under the REACH Regulation, chemical risk (or safety) assessment involves up to six steps: (1) human health hazard assessment, (2) human health hazard assessment of physicochemical properties, (3) environmental hazard assessment, (4) PBT and vPvB assessment, and, for hazardous substances also, (5) exposure assessment, including the generation of exposure scenario(s) and exposure estimation, and (6) risk characterisation.[190] The REACH Regulation accommodates possible limited exceptions in relation to "particular effects" for which these steps are "impracticable."[191] In such cases, "the risks associated with such effects shall be assessed on a case-by-case basis and the manufacturer or importer shall include a full description and justification of such assessments in the chemical safety report and summarised in the safety data sheet."[192]

The proponents invoke this exception based on the argument that "these PFASs are very persistent (vP) in combination with identified and possible other concerns." Therefore, they state, "the risk is described on a case-by-case basis."[193] To further bolster their case for an exception, they repeat their hypothesis that as long as PFASs will continue to be used, emissions will continue, environmental stocks will increase, and environmental or health harm will ensure once thresholds will be exceeded, either by single PFAS or through combined effects.

Their argument reflects a fundamental misunderstanding of the nature and scope of the exception, however. Rather than demonstrating that the various steps of chemical risk assessment required by the REACH Regulation are "impracticable" for the "particular effect" of PBT or vPvB, they argue that the entire REACH Regulation should be rewritten to incorporate a novel concept of assessment of hypothetical persistence-related risks posed by a large, open-ended class of substances that loosely hangs together, based on assumptions, worst-case scenarios, and precaution. This argument is as irrelevant as it is disingenuous. The REACH Regulation's explicit requirements on PBT/vPvB assessment cannot be overridden by a desire for broader regulatory powers.

3) Case-by-case persistence assessment?

Insofar as the REACH Regulation provides for specific rules for PBT/vPvB assessment, the legal standards are to be applied with those specific rules in mind. As the Court found, "the EU legislature laid down clear criteria in Annex XIII for the identification of PBT and vPvB

[189] Global Silicones Council and Others v European Commission, Case T-226/18, 30 June 2021, para. 192-199, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62018TJ0226
[190] Section 0.6.1, Annex I, REACH Regulation.
[191] The effects that are identified explicitly include "ozone depletion, photochemical ozone creation potential, strong odour and tainting."
[192] Section 0.10, Annex I, REACH Regulation.
[193] PFAS Proposal, p. 47.

substances. That annex reflects the legislature's view that a substance which meets the criteria for identifying PBT or vPvB substances is of very high concern. The legislature did not provide for any additional assessment for substances meeting those criteria with a view to ascertaining whether they are more or less 'reversible' than other PBT and vPvB substances."[194]

This court judgment in essence provides that the rules regarding PBT/vPvB assessment set forth in the REACH Regulation are to be followed, except if exceptions apply. The proponents of the PFAS restrictions have not demonstrated that any exceptions apply, however.

4) Non-precautionary, science-based assessment

Further, both quantitative and qualitative risk assessment must be based on scientific evidence and limited to a scientific assessment, to the exclusion of value-laden policy judgments. As the Commission has emphasized, the precautionary principle may play a role in risk management, but not in risk assessment.[195]

From the perspective of science-based regulation, this is a necessary condition for both the proper functioning of science and risk assessment, on the one hand, and policymaking and risks management, on the other hand. In other words, precautionary risk assessment is not an acceptable practice (for further discussion, see below).

iv. Proportionality

1) General EU law

Under the principle of proportionality, "the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties."[196] The proportionality principle has been worked out by the European courts. In *Fedesa*, the Court articulated the principle as follows: "By virtue of that principle, the lawfulness of the prohibition of an economic activity is subject to the condition that the prohibitory measures are appropriate and necessary in order to achieve the objectives legitimately pursued by the legislation in question; when there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued."[197] The principle applies to both EU and Member State measures.

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[194] Global Silicones Council and Others v European Commission, Case T-226/18, 30 June 2021, para. 125, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62018TJ0226
[195] European Commission, Communication on the Precautionary Principle, COM(2000) 1 final , Brussels, 2.2.2000, https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:en:PDF
[196] Article 5(4), Treaty on European Union (TEU).
[197] Case C-331/88, The Queen v Ministry of Agriculture, Fisheries and Food, ex parte FEDESA and Others, Judgment of the Court (Fifth Chamber) of 13 November 1990, https://curia.europa.eu/juris/liste.jsf?language=en&num=C-331/88

Thus, the principle has four components: (1) a measure must be appropriate to achieve a desired end, (2) it must be necessary to achieve that end, (3) there is no less onerous measure that achieves that objective, and (4) the burdens imposed by the measure may not be disproportionate. The intensity of judicial review of compliance with the proportionality principle varies, and in many cases the Court defers to the EU legislature's judgment, in particular where it exercises broad discretion involving political, economic or social choices requiring it to make complex assessments.[198] The EU's wide margin of assessment has also been confirmed with respect to environmental protection.[199] To maintain the institutional balance,[200] the Court has often rejected challenges based on proportionality on the ground that a measure was not "manifestly disproportionate" and that the Court should not substitute its judgment for that of the EU legislature.[201]

Where the Court finds that the EU enjoys broad discretion in exercising its powers "in an area of evolving and complex technology," it limits its review to "verifying whether the exercise of such powers has been vitiated by a manifest error of appraisal or a misuse of powers, or whether the legislature has manifestly exceeded the limits of its discretion."[202] In this context, the EU judiciary is reluctant to substitute "its assessment of scientific and technical facts for that of the EU legislature on which the Treaty has conferred that task." On the other hand, when the EU legislature "has to assess the future effects of legislation to be enacted although those effects cannot be accurately foreseen, its assessment is open to criticism only if it appears manifestly incorrect in the light of the information available to it at the time of the adoption of the legislation in question."[203]

In case the Court resorts to limited review of proportionality, it often employs more rigorous "process-oriented review," also referred to as "procedural proportionality."[204] As the Court put it in Poland v. Commission in 2018, "even judicial review of limited scope requires that the EU institutions that have adopted the act in question must be able to show before the Court that in adopting the act they actually exercised their discretion, which presupposes the taking into consideration of all the relevant factors and circumstances of the situation the act was intended to regulate. It follows that those institutions must at the very least be able to produce and set out clearly and unequivocally the basic facts which had to be taken into account as the basis of the contested measures of the act and on which the exercise of

[198] Case C-491/01, British American Tobacco (Investments) and Imperial Tobacco, Judgment of the Court of 10 December 2002, https://curia.europa.eu/juris/liste.jsf?language=en&num=C-491/01
[199] Case C-343/09, Afton Chemical, Judgment of 8 July 2010, EU:C:2010:823.
[200] The "balance of powers" in the case law goes back to the 1958 *Meroni* case. Meroni v. High Authority, Judgment of 13 June 1958, EU:C:1958:7. Cf. Article 19(1) TEU: "[The Court of Justice] shall ensure that in the interpretation and application of the Treaties the law is observed."
[201] Case C-34/08, Azienda Agricola Disarò Antonio and Others, Judgment of the Court (First Chamber) of 14 May 2009, https://curia.europa.eu/juris/liste.jsf?language=en&num=C-34/08
[202] Case C-128/17, judgment of 21 June 2018, Poland v Parliament and Council, EU:C:2019:194.
[203] Case C-310/04, Spain v. Council, judgment of 7 September 2006, EU:C:2006:521, https://curia.europa.eu/juris/liste.jsf?language=en&num=C-310/04 Retrospective assessment of a law's efficacy based on new facts, hence, may be rejected. Case C-101/12, Schaible, Judgment of the Court (Fifth Chamber), 17 October 2013, https://curia.europa.eu/juris/liste.jsf?num=C-101/12&language=EN
[204] K. Lenaerts, The European Court of Justice and Process-Oriented Review, Yearbook of European Law, Vol. 31, No. 1, 2012, pp. 3-16.

their discretion depended."[205] Based on this kind of proportionality review, the Court found that the reform of the support scheme for cotton violated the proportionality principle.[206]

2) *Proportionality in the PFAS Proposal*

The EU Treaty on the Functioning of the European Union (TFEU) instructs the Commission in developing its proposals concerning health, safety, and environmental protection, to take into account "any new development based on scientific facts."[207] Further, it stipulates that in preparing its policy on the environment, the EU must "take account of "available scientific and technical data" and "the potential benefits and costs of action or lack of action."[208] Likewise, under the restrictions procedure set forth in the REACH Regulation, the "socio-economic impact of the restriction, including the availability of alternatives" is to be taken into account.

3) *Limited impact analysis*

The PFAS proposal discusses the costs and benefits of the proposed restriction and the availability of alternatives to a limited extent. This discussion is chiefly qualitative, with some quantifications of varying reliability. Risk assessments of the alternatives to PFAS substances are conspicuously absent, however, which means that the costs of alternatives are systematically grossly underestimated. This is a major deficiency because it may result not just in imposing unnecessarily high economic cost on society, but also in actual increased risk levels to which workers, consumers and the environment may be exposed.[209]

An example is the use of PFAS substances as catalysts in the production of polymers.[210] In a number of applications, a PFAS catalyst increases process efficiency, reduces impurities, and increases material performance, which, in turn, results in energy savings, lower emissions, superior product performance, lower accident rates, and economic savings. If these catalysts are banned, alternatives such as metal oxides or metal sulfides may have to be

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[205] Case C-626/18, Poland v Parliament and Council, Judgment of the Court (Grand Chamber) of 8 December 2020, https://curia.europa.eu/juris/liste.jsf?num=C-626/18 Cf. Judgment of 3 December 2019, Czech Republic v Parliament and Council, C-482/17, EU:C:2019:1035.

[206] Case C-310/04, Spain v. Council, Judgment of 7 September 2006, EU:C:2006:521. But cf. Vodafone, Case C-58/08, Judgment of 8 June 2010, EU:C:2010:321.

[207] Article 114(3), TFEU. "Within their respective powers, the European Parliament and the Council will also seek to achieve this objective."

[208] Article 191(3) TFEU. "[T]he economic and social development of the Union as a whole and the balanced development of its regions" must also be taken into account."

[209] See John D. Graham & Jonathan Baert Wiener, Risk vs. Risk: Tradeoffs in Protecting Health and the Environment, Harvard University Press, 1997.

[210] See, for instance, Minna Hyytiäinen, Patrik Appelblad, Einar Pontén, Malin Stigbrand, Knut Irgum, Hans Jaegfeldt, Trifluoromethanesulfonic acid as a catalyst for the formation of dansylhydrazone derivatives, Journal of Chromatography A, Volume 740, Issue 2, 1996, pp. 279-283, ISSN 0021-9673, https://doi.org/10.1016/0021-9673(96)00256-7, https://www.sciencedirect.com/science/article/pii/0021967396002567 Adeeb Hayyan et al., Esterification of sludge palm oil using trifluoromethanesulfonic acid for preparation of biodiesel fuel, Korean Journal of Chemical Engineering, April 2013, 30:1-6, DOI: 10.1007/s11814-013-0045-4 D.O. Bennardi, G.P. Romanelli, J.C. Autino, L.R. Pizzio, Trifluoromethanesulfonic acid supported on carbon used as catalysts in the synthesis of flavones and chromones, Catalysis Communications 10 (2009) 576–581.

used, which may result in exposure to known CMR substances, even if adequate control is ensured, higher energy use, higher emissions, increased unwanted by-products and wastes, lower material performance, lower product performance, higher accident rates, and higher costs. As a consequence of not engaging in any detailed analysis of specific uses of PFAS compared to any alternatives that meet the same need, and, thus, ignoring trade-offs, the PFAS proposal may well cause that which it hopes to prevent: regrettable substitution.[211]

4) Cost-effectiveness analysis

The main report sets forth a section on proportionality,[212] and annexes present an impact assessment[213] and information on assumptions, uncertainties and sensitivities.[214] Despite the significant number of pages dedicated to these issues, the analysis of the cost and benefits of the proposed restriction and the assessment of proportionality is rudimentary and self-serving. None of this is a surprise, of course; no government could hope to produce relative risk assessments and cost-benefit analyses of over 10,000 substances (an unknown number of which do not even currently exist) and all of their alternatives in hundreds, if not thousands, of applications.

The proponents of the proposal attempt to downplay the importance of the assessment of alternatives, impact analysis, and proportionality assessment. To this end, they argue that "the standard approach adopted to assess proportionality of PBT/vPvB chemicals is a cost effectiveness analysis (CEA), assuming that cost-benefit analysis cannot be used due to a lack of safe concentration levels of PBT/vPvB chemicals."[215] Thus, the non-threshold nature of PBT/vPvB substances is invoked to justify refraining from cost/benefit analysis.

CEA is no substitute for cost/benefit analysis, however, because it focuses merely on "the least cost means of achieving pre-set targets or goals," which implies that any cost will be

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[211] Cf. Hanekamp J., Bergkamp L., European Food Law and the Precautionary Principle – Paradoxical Effects of the EU's Precautionary Food Policies, in: Kai Purnhagen & Harry Bremmers, Regulating and Managing Food Safety in the EU, Springer Verlag, 2018, pp. 217-244.For a discussion of 'smart substitution', see Royal Society of Chemistry, Environment, Health and Safety Committee, Exploring the Practical Aspects of Chemical Substitution, 2007, https://substitution.ineris.fr/sites/substitution-portail/files/documents/rsc_2007.pdf Jacobs MM, Malloy TF, Tickner JA, Edwards S. 2016. Alternatives assessment frameworks: research needs for the informed substitution of hazardous chemicals. Environ Health Perspect 124:265–280, http://dx.doi.org/10.1289/ehp.14095

[212] Section 2.4.4, PFAS Proposal.

[213] Annex E, Impact assessment, https://echa.europa.eu/documents/10162/8de11d7c-c56f-e204-5072-e89f11071219

[214] Annex F, Assumptions, uncertainties and sensitivities, https://echa.europa.eu/documents/10162/290b67b0-f592-a78a-1854-e2574d675c4a

[215] PFAS Proposal, p. 159. Reference is made to ECHA, Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC. SEAC/31/2016/05 Rev.1. European Chemicals Agency, 2016, https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpvb_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3 ("Quantification of impacts is not currently possible for most PBT/vPvB substances, which makes the evaluation of the proportionality to the risks of the proposed restriction or whether the socio-economic benefits of use of the substance outweigh the risks1 for an application for authorisation challenging.")

deemed acceptable to achieve the target.[216] CEA does no more than help to find "the minimum cost of meeting a specified physical outcome," and, because it "does not require monetising the benefit of achieving a target," it provides no assurance that achieving any target will result in net benefits."[217] Thus, contrary to the requirements of the EU treaty and REACH Regulation, CEA cannot support a sound analysis of the potential benefits and costs of action or lack of action, nor of the socioeconomic impact of the proposed restriction.

5) Restriction and proportionality

As discussed above,[218] the requirements set forth in the REACH Regulation's provisions on restrictions are also intended to ensure that any restriction is proportional. In particular the requirement that the socio-economic impact of the restriction and the availability of alternatives be taken into account, should guard against disproportionate restrictions. An assessment of the availability of alternatives, of course, requires also an assessment of the performance and risks posed by any alternative, i.e., of its costs and benefits, which can then be compared to those of the PFAS substance it substitutes for.

The PFAS proposal disappoints in this regard, however. Although ECHA guidance suggests that socio-economic impact analysis cover "the net benefits to human health and the environment and the net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole," 'including "reduced risk due to restriction and possible risks caused by the transfer to alternatives,"[219] the PFAS proposal provides little reliable information on these key aspects. It fails to properly identify and assess the costs to society of the proposed bans and does not consider negative impacts on product performance, safety, trade and investment. In particular, it does not consider the costs associated with the lack of acceptable alternatives to PFAS substances in many applications. Accordingly, the proposed restriction may well go beyond what is necessary to achieve any legitimate objectives pursued by it and may not be the least restrictive means to achieve these objectives.

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[216] "Cost-effectiveness analysis (CEA) is widely used to support decision making by determining the least cost means of achieving pre-set targets or goals. It is often defined in terms of finding the minimum cost of meeting a specified physical outcome." ECHA, Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC. SEAC/31/2016/05 Rev.1. European Chemicals Agency, 2016, https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpvb_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3

[217] ECHA, Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC. SEAC/31/2016/05 Rev.1. European Chemicals Agency, 2016, https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpvb_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3

[218] See Sections 2.b and 3.a., above.

[219] ECHA, Guidance for the preparation of an Annex XV dossier for restrictions, 2007, https://echa.europa.eu/documents/10162/2324906/restriction_en.pdf/d48a00bf-cd8d-4575-8acc-c1bbe9f9c3f6, p. 79. See also ECHA Guidance on Socio-Economic Analysis – Restrictions, May 2008, https://www.echa.europa.eu/documents/10162/2324906/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d

6) No proportionality analysis is possible

To justify their proposal, the proponents count heavily on ECHA's lax attitude towards costs/benefit analysis. In the impact assessment, they even acknowledge that "[b]ased on the available evidence about impacts, it is for most sectors not feasible to conclude about proportionality." In the absence of any such conclusions, it is questionable whether the legal standards are met. If no proportionality analysis is possible, no restriction is possible, at least not lawfully.

To fill the void, the proponents invoke "other arguments" that "can be relevant to underline a conclusion on the proportionality of restriction options." These excuses include the fact that "[a]ll PFASs in the scope of this restriction proposal are either very persistent themselves or degrade into very persistent PFASs in the environment," and that "[i]f releases are not minimised, the environmental stock will continue to increase in the future," and "[a]s a consequence, humans and other organisms will be exposed to progressively increasing amounts of PFASs." They also claim that "[t]here is a potential for long-term, intergenerational effects and a late detection of adverse effects after PFAS exposure," and "[s]ignificant societal costs can be expected from a continued PFAS use and emissions of PFASs in the form of loss of natural resources and environmental quality and functioning, as well as health costs[220] and/or massive remediation/purification costs." [221]

Thus, while the proponents speculate about potential adverse effects of PFAS substances, they pay little attention to their actual benefits. How such speculation could be deemed to meet the proportionality requirements imposed by EU law remains a mystery.

7) Lack of evidence of adverse effects

The adverse effects of continued use of PFAS on human health, likewise, is not quantified in the PFAS proposal. The reasons for the lack of quantification, however, also reveal a lack of reasonable certainty about any adverse effects: "limited, or missing, data to assess the hazard of many of the individual PFAS substances" and "the associated thresholds below which exposure is not expected to lead to adverse health effects, if such limits exist."[222] On these grounds, the proponents consider that a ban without exceptions "could be proportionate in the medium and long-term due to the expected progressively increasing amounts of PFASs that would be emitted without a ban." This would be so because "[s]ocietal costs associated with a continued use of PFASs will likely progressively increase as

[220] With reference to a report published by the Nordic Council of Ministers, it is alleged that "the annual health costs of exposure to PFAS in Europe *could be* between €52 and €84 billion." (Emphasis supplied.) Goldenman G., Fernandes M., Holland M., Tugran T., Nordin A., Schoumacher C., and McNeill A, The cost of inaction: A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS. Nordic Council of Ministers, Copenhagen, 2019, DOI:10.6027/TN2019-516

[221] Annex E, Impact assessment, https://echa.europa.eu/documents/10162/8de11d7c-c56f-e204-5072-e89f11071219, pp. 517-518.

[222] Other reasons mentioned in the annex are lack of data on "the combined effects of co-occurring PFASs, and the prediction of future human exposure levels." PFAS Proposal, p.180. Cf. Annex E, Impact assessment, https://echa.europa.eu/documents/10162/8de11d7c-c56f-e204-5072-e89f11071219, pp. 517-518.

well and eventually outweigh the societal costs of" a ban. A ban with time-limited exceptions, however, is the "most appropriate option" that would "balance[e] the trade-offs."[223]

Why this would be so, however, remains an open question. In the absence of evidence of adverse effects on so many substances covered by the proposed PFAS restriction, how could the inclusion of those substances be deemed "proportional"? If evidence of adverse effects at some point in the future becomes available for specific PFAS substances, an appropriate restriction can be considered at that point. Pre-emptive restriction of substances based on fear that they might cause adverse effects in the future cannot be regarded as proportional under EU law and the REACH Regulation.

8) Uncertainties

Although many significant uncertainties are identified by the proponents, these do not change their judgment on the necessity, effects, and proportionality of the PFASs ban they are seeking. The uncertainties relate to both the basic facts ("is there a risk?" and "what is the extent of the problem?"[224]) and the costs and benefits of the proposed ban ("is the proposed restriction of overall benefit to society?"[225]).

The proponents admit, for instance, that "[f]or some sectors the level of uncertainty will vary from use to use within the sector," and that "uncertainty in the proportionality assessment is negligible for all uses" in only three sectors: (i) consumer mixtures ("[a]lternatives are already present in the market at competitive prices"), (ii) cosmetics ("alternatives are available at competitive prices and are already in very wide use" and "reformulation costs are expected to be small") and (iii) ski waxes ("alternatives are available and have been accepted by sporting bodies for use in competition").[226] The proposed ban, however, extends far beyond these sectors and uses.

9) Disproportionality of scope

The PFAS proposal concludes that "the proposed restriction would be of overall benefit to society, recognising the consequences of continual use and emissions of PFASs into the future and the availability of viable alternatives for many uses."[227] While it cannot be excluded that a more targeted and limited PFAS restriction focused only on those substances that are known to be hazardous and to pose serious risks could be proportional, they proponents cannot substantiate their proposition that there is "overall benefit to society" of the overly broad PFAS ban they advocate.

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[223] PFAS Proposal, p.180.
[224] PFAS Proposal, p. 187.
[225] PFAS Proposal, p. 188. See also Annex F, Assumptions, uncertainties and sensitivities, https://echa.europa.eu/documents/10162/290b67b0-f592-a78a-1854-e2574d675c4a
[226] Annex F, Assumptions, uncertainties and sensitivities, https://echa.europa.eu/documents/10162/290b67b0-f592-a78a-1854-e2574d675c4a, p 7.
[227] PFAS Proposal, p. 189.

The proponents could reach a positive conclusion on the proportionality of the proposed broad ban only because they paint with a broad brush and use generalizations without a basis in fact,[228] fail to analyze costs and benefits for each substance, sector, and use separately, downplay the substantial costs associated with the proposed ban, tend to inflate the relatively small benefits generated by the restriction,[229] and invoke the possibility, not the probability, of enormous harm in the future, not the present, to find the proposed ban proportional. Where the proponents acknowledged the substantial uncertainties that "may affect the quality of the conclusions reached," they use this to impose the burden of proof on stakeholders.[230] Implicitly they acknowledge that the scope of their proposal is disproportional, but they apparently intend to fix it by granting exemptions upon request if sufficient justification is provided. This way of proceeding is incompatible with EU law and the REACH Regulation.

In this regard, the PFAS proposal is reminiscent of the so-called "Dismal Theorem," which has been posited in connection with climate change.[231] These issues will be discussed further in relation to the precautionary principle in Section 3.b.vi, below.

v. Fundamental rights

The PFAS Proposal also raises legal issues with respect to fundamental and human rights. The EU recognizes the rights, freedoms and principles set out in the Charter of Fundamental Rights.[232] The Charter protects the rights not only of natural persons, but also of corporate legal persons.[233] This does not mean that fundamental rights apply in exactly the same manner to corporations as they do to natural persons, or that each of the rights are relevant

[228] "Ecotoxicity and endocrine activity and effects on human health are documented in Annex B.5. and Annex B.7. for a range of PFASs. Studies show the increasing evidence for effects of low exposures and combined exposures and potential for intergenerational effects (Annex B.4.2.9., B.5.1. and B.7.1.). It is acknowledged that experimental data is limited for many PFASs, in part a consequence of the size of the group of chemicals. However, there is a substantial body of evidence available that demonstrates the risks of PFAS exposure." PFAS Proposal, p. 187.

[229] "Removal of contamination is technically challenging, energy intensive, and thus costly. Additionally, costs of health care, loss of biodiversity, loss of ecosystem services and loss of property value (Cousins et al., 2020b) need to be taken into account. Therefore, a preventive approach of not using highly persistent synthetic organic substances is more protective and also overall less costly for society." Annex XV Restriction Report, PFASs, 22 March 2023, p. 50. "The overall annual health costs following from exposure to PFAS in Europe has been estimated in a Nordic Council report from 2019 to be between €52 and 84 billion." Annex XV Restriction Report, PFASs, 22 March 2023, p. 3.

[230] "Consultation on the dossier provides an opportunity for stakeholders to provide further substantiated information to reduce these uncertainties." PFAS Proposal, p. 189.

[231] Weitzman, M.L., On modelling and interpreting the economics of catastrophic climate change, Rev. Econ. Stat., 91 (1), 2009, pp. 1-19.

[232] Article 6, TEU. Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, pp. 391–407. The Preamble to the Charter states that "it is necessary to strengthen the protection of fundamental rights in the light of changes in society, social progress and scientific and technological developments by making those rights more visible in a Charter."

[233] This is consistent with the common constitutional traditions of the member states, as well as the European Court of Human Rights' stance.

to both natural and legal persons. In some instances, the rights of corporations may be considered derivative of the corresponding individual rights. For example, protecting the existence of an organization as a legal entity may be necessary to secure the freedom of association of its members, or requiring compensation when a company is deprived of its property may be necessary to protect freedom of that company's owners or shareholders to peacefully enjoy their property. One of the fundamental rights is non-discrimination. It is settled case-law that the principle of non-discrimination requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified.[234]

These rights are not absolute and limitations are permitted. Article 52 of the Charter provides that "[a]ny limitation on the exercise of the rights and freedoms recognized by this Charter must be provided for by law and *respect the essence of those rights and freedoms*. Subject to the principle of *proportionality*, limitations may be made only if they are *necessary and genuinely meet objectives of general interest* recognized by the Union or *the need to protect the rights and freedoms of others*."[235] The "essential core" doctrine set forth in this provision is independent from the proportionality principle.[236] Further, the Charter sets forth rights (hard claims) and principles (soft claims). Article 52(5) adds that "[t]he provisions of this Charter which contain *principles* may be implemented by legislative and executive acts taken by institutions, bodies, offices and agencies of the Union, and by acts of Member States when they are implementing Union law, in the exercise of their respective powers. They shall be *judicially cognizable only in the interpretation of such acts and in the ruling on their legality*."[237] The Charter does not specify, however, which provisions embody "rights" and which "principles" – each provision "may contain both elements of a right and of a principle."[238]

1) Authority to restrict fundamental rights

Under the Charter of Fundamental Rights, the PFAS proposal raises issues in relation to authority and substance. As far as authority is concerned, the PFAS Proposal would be enacted as secondary legislation pursuant to the REACH Regulation.

The Court of Justice has held, however, that the Treaty of the Functioning of the EU requires the involvement of the EU legislature if fundamental rights are restricted "to such an extent

[234] Case C-273/04 Poland v Council [2007] ECR I-8925, paragraph 86 and the case-law cited.
[235] The second and third paragraph of Article 52 of the Charter provide as follows:
"2. Rights recognised by this Charter which are based on the Community Treaties or the Treaty on European Union shall be exercised under the conditions and within the limits defined by those Treaties.
3. In so far as this Charter contains rights which correspond to rights guaranteed by the Convention for the Protection of Human Rights and Fundamental Freedoms, the meaning and scope of those rights shall be the same as those laid down by the said Convention. This provision shall not prevent Union law providing more extensive protection."
[236] Case C-293-12, Digital Rights Ireland Ltd., Judgment of 8 April 2014, and Case C-547/14, Philip Morris, Judgment of 4 May 2016.
[237] Article 52(5),
[238] EXPLANATIONS RELATING TO THE CHARTER OF FUNDAMENTAL RIGHTS, 2007/C 303/02, 2007 OJ C 303/17, 14.12.2007, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007X1214(01)&from=EN

that the involvement of the EU legislature is required."[239] This circular argument raises a question as to whether fundamental rights may be restricted by secondary legislation under the REACH Regulation; if such rights are indeed restricted, the EU legislature would need to be involved. A strong argument can be made that with respect to those substances as to which there is no evidence of adverse effects, fundamental rights are breached.

2) Infringement of substantive rights

The substantive question thus is whether the PFAS proposal restricts any fundamental rights. On its face, the PFAS proposal would indeed appear to have restrictive effects on several fundamental freedoms and rights, and therefore require not only a compelling and democratically legitimate justification, but also the legislature's involvement.[240]

The following human rights would appear to be at risk if the PFAS proposal were adopted. First, the freedom to conduct a business in accordance with Community law and national laws and practices would be restricted.[241] Likewise, the right to property would be at stake if the rules imposed by the PFAS restrictions are deemed to go further than "is necessary for the general interest."[242]

Whether the PFASs bans with its derogations and arbitrary scope limitations is consistent with the equality and non-discrimination principle is also an open question.[243] For instance, the microplastic restriction, which is also a very broad measure, does not restrict all plastics, but only microplastics that are deemed to create risk, i.e., i.e., microplastics that meet objective biodegradability and solubility criteria[244] – the PFAS restriction goes way beyond this and restricts all PFAS substances, irrespective of any risk.

Further, ECHA and the other EU institutions are required to comply with the right to good administration and handle the affairs of the PFAS stakeholders "impartially, fairly and within a reasonable time."[245] This principle requires also that decisions be based on careful fact-finding, not speculation. The PFAS proposal falls short of these requirements.

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[239] Case C-696/15 P, Czech Republic v European Commission, Judgment of the Court (Fourth Chamber) of 26 July 2017, https://curia.europa.eu/juris/liste.jsf?language=en&num=C-696/15
[240] Cf. Stibernitz, B. (2012). A Brief Comment on Science-based Risk Regulation Within the European Union. European Journal of Risk Regulation, 3(1), 86-91. doi:10.1017/S1867299X00001847
[241] Article 16, Freedom to conduct a business, Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, pp. 391–407.
[242] Article 17, Right to property, Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, pp. 391–407.
[243] Article 20, Equality before the law, Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, pp. 391–407.
[244] COMMISSION REGULATION (EU) …/… of XXX amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles, https://ec.europa.eu/transparency/comitology-register/screen/documents/083921/6/consult?lang=en
[245] Article 41, Right to good administration, Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, pp. 391–407.

3) Conclusions

In short, a colorable, if not strong, argument can be made that the PFAS proposal restricts the rights discussed above without adequate justification by imposing severe restrictions on the manufacture and use of a wide range of substances. As a result thereof, the freedom to conduct a business in the chemical sector is severely restricted and the right to property is restricted beyond what is necessary in the general interest.

Since these restrictions depend on the substances concerned, and for some businesses will be severe, but for other businesses minimal or non-existent, without there being an objective justification for making these distinctions, the principle of equality before the law may also be violated. Moreover, as the PFAS proposal would restrict fundamental rights, it cannot be adopted by the Commission and requires involvement of the EU legislature.

b. Methodology and Reasoning in the PFAS Proposal

A closer analysis of the analytical structure of the argument made by the proponents of the PFAS proposal demonstrates how far they have strayed from the science- and rule-based regulatory decision-making processes dictated by the REACH Regulation. Scrutiny of the steps in their argument scatters any confidence that the reasoning of the proponents is tight, logical, and consistent with the applicable legal provisions. As discussed in preceding sections, from the perspective of scientific methodology, their argument does not only not impress, but fails to answer the most basic questions that it raises.

i. Dose-response relations

Ever since Paracelsus, it has been known that the dose determines whether a substance is a poison.[246] While response is a function of dose, critical dose levels for PFAS substances are not addressed anywhere in the PFAS proposal. Rather, the proponents repeat several times that if PFAS emissions continue, environmental stocks will continue to increase, inevitably biological thresholds will be exceeded, and serious mischief will ensue. There is no critical discussion of the constituent elements of this hypothesis, and the scientific evidence that contradicts or is inconsistent with it is either ignored or brushed aside.

Instead, to support their radical proposal, the proponents refer to a small group of scientists that have expressed serious concerns about all PFAS substances, but their work does not resolve the key scientific issues. Rather, as discussed further below, they treat scientific uncertainty and fear about possible adverse effects as justification for normative prescriptions that are not based on science.[247]

[246] Bruce N. Ames and L.S. Gold, Paracelsus to Parascience: The Environmental Cancer Distraction, Mutation Research 447, 2000, pp. 3-13. Cf. L.S. Gold, T.H. Slone, N.M. Manley and B.N. Ames, Misconceptions about the causes of cancer, Fraser Institute, Vancouver, 2003. Bruce Ames & Lois Swirsky Gold, Cancer prevention and the environmental chemical distraction, in: M. Gouch (editor), Politicizing Science: The Alchemy of Policymaking, Hoover Instituton Press, 2003.
[247] See further Section 3.b.ii, above.

ii. Causation

Furthermore, criteria for determining causal relations, essential elements of the scientific method, are not applied. The Bradford-Hill criteria, for instance, provide principles that help to assess the strength of putative causal relations. These criteria include strength, consistency, specificity, temporality, biological gradient, plausibility, coherence, experiment, and analogy.[248] There are other ways of evaluating causal links, such as counterfactuals and confounding variables.

The PFAS proposal, however, does not apply any rigorous method to determine causal links and proceeds chiefly on the basis of what in science would be called conjecture. As discussed further below, the grouping approach and "read-across" strategy employed by the proponents is not based on any adequate scientific data, has not been scientifically validated, and ignores the criteria for read-across justifications set forth in the REACH Regulation. Likewise, the use of persistence as proxy for hazard, and emissions as a proxy for exposure to hazard, and, thus, risk, is scientifically invalid for the broad group of substances covered by the PFAS definition.

iii. Conditions for restriction

From a legal perspective, the reasoning of the proponents of the PFAS ban represents an attempt to fake the fulfillment of the conditions imposed by the REACH Regulation for the imposition of restrictions. Except where REACH accommodates grouping or read-across (which itself is subject to conditions and requirements), the REACH conditions will have to be met for each substance included in the group subject to the ban. Whether this, as a matter of fact, is the case, is discussed further below in connection with grouping.

The reasoning on which the PFAS restriction appears to be based is complicated and convoluted. If the common component of the PFASs substances is regarded as the cause of both persistence and toxicity (or bioaccumulation in the case of vPvB), evidence to this effect would be required. If the common component is deemed to be only the cause of persistence, but not of toxicity (based on the theory that toxicity is not a condition), the question arises how that could result in finding this "risk" is "unacceptable," as the REACH Regulation requires.

[248] Hill, Austin Bradford, The Environment and Disease: Association or Causation?, Proceedings of the Royal Society of Medicine, 1965, 58 (5), pp. 295–300. For critical analyses of these criteria, see Schünemann H, Hill S, Guyatt G; et al., The GRADE approach and Bradford Hill's criteria for causation, Journal of Epidemiology & Community Health, 2011, 65 (5), pp. 392–95. Höfler M., The Bradford Hill considerations on causality: a counterfactual perspective?, Emerging Themes in Epidemiology, 2005, 2 (1): 11. Howick J, Glasziou P, Aronson JK, The evolution of evidence hierarchies: what can Bradford Hill's 'guidelines for causation' contribute?". Journal of the Royal Society of Medicine, 2009, 102 (5), pp. 186–94.

iv. Burden of proof

There are some further issues that need to be addressed too. For instance, should these conditions be verified only for the restriction as proposed, or also for other alternative measures that have not been considered? Importantly, in relation to the burden of proof, what is the default position – do the proponents have to prove that these conditions are met with respect to each substance covered by the proposed restriction, or is a regulated entity required to prove that with respect to a specific PFAS substance, the conditions are not met? Would it be acceptable for the regulator to preclude any such evidence and work with irrebuttable presumptions of risk and harm?

Below, these issues are discussed further. The proponents of the PFAS ban appear to have employed a methodology that anticipates (or is inspired by) some of the proposed changes that are being considered in connection with the forthcoming revision of the REACH Regulation.[249] The question arises whether this kind of anticipatory application is lawful under EU law.

v. PFAS Definition

As discussed in Section 2.c, above, the PFAS proposal incorporates the definition developed by the OECD. It includes a wide range of widely different substances: (i) HFC/HFO fluorocarbons (C2-C4), (ii) the entire OECD PFAS C4-C14 library of approx. 4,700 chemicals, and (iii) PCTFE fluoropolymers with a molecular weight of approx. 249,000.[250] The proponents of the PFAS restriction fail to recognize, however, that the OECD definition, as the OECD states explicitly, was not intended to be used for group-wide regulation of PFAS substances. To the contrary, the OECD's report specially warns against any such use:

> "The decision to broaden the definition compared to Buck et al. is not connected to decisions on how PFASs should be grouped in regulatory and voluntary actions. … As PFASs are a chemical class with diverse molecular structures and physical, chemical and biological properties, it is highly recommended that such diversity be properly recognized and communicated in a clear, specific and descriptive manner. The term "PFASs" is a broad, general, non-specific term, which does not inform whether a compound is harmful or not, but only communicates that the compounds under this term share the same trait for having a fully fluorinated methyl or methylene carbon moiety."[251]

[249] Chemicals: Commission seeks views on revision of REACH, the EU's chemicals legislation, Jan. 20, 2022, available at https://environment.ec.europa.eu/news/chemicals-commission-seeks-views-revision-reach-eus-chemicals-legislation-2022-01-20_en

[250] OECD, Portal on per and poly-fluorinated chemicals, https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/

[251] OECD, Reconciling Terminology of the Universe of Per-and Polyfluoroalkyl Substances: Recommendations and Practical Guidance. OECD Environment, Health and Safety Publications, Series on Risk Management No. 61. Organisation for Economic Co-operation and Development, 2021, https://one.oecd.org/document/ENV/CBC/MONO(2021)25/En/pdf, p. 8.

1) *From description to prescription*

Thus, the OECD definition is descriptive, not intended to identify hazard or risk, but merely to describe a large, diverse group of substances with a common group, and not intended for regulatory purposes, let alone restrictions. To avoid any doubt, the OECD adds that its definition "does not conclude that all PFASs have the same properties, uses, exposure and risks," "may be viewed as too broad, encompassing thousands or more compounds, for anyone to address all of them at once," and merely "serves as a starting and reference point to guide individual users to have a comprehensive understanding of the PFAS universe."[252]

The proponents of the PFAS proposal have completely ignored the OECD's caveats and did exactly what the OECD advised against: they use the broad PFAS definition intended for the sole purpose of a "comprehensive understanding the universe of PFAS," to impute similar properties to diverse groups of PFAS chemicals for the purpose of regulating them in one big sweep. For instance, as discussed, fluoropolymers and F-gases should be viewed as separate categories from a toxicological perspective.[253] These are major deficiencies that are aggravated by other deviations from rigorous methodology.[254]

4) *Presumed common properties*

According to the proponents, the PFASs substances that would be subject to the restriction are either persistent themselves or degrade to persistent PFASs. Due to its diversity, however, the group of PFASs substances cannot be characterized by a specific range of physicochemical properties. Nevertheless, the proponents assert, these substances or their PFAS degradation products "share very high persistence as a common characteristic."[255]

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[252] OECD, Reconciling Terminology of the Universe of Per-and Polyfluoroalkyl Substances: Recommendations and Practical Guidance. OECD Environment, Health and Safety Publications, Series on Risk Management No. 61. Organisation for Economic Co-operation and Development, 2021, https://one.oecd.org/document/ENV/CBC/MONO(2021)25/En/pdf , p. 25.

[253] Cf. Henry BJ, Carlin JP, Hammerschmidt JA, Buck RC, Buxton LW, Fiedler H, Seed J, Hernandez O. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag. 2018 May;14(3):316-334. doi: 10.1002/ieam.4035 ("[F]luoropolymers are distinctly different from other polymeric and nonpolymeric PFAS and should be separated from them for hazard assessment or regulatory purposes. Grouping fluoropolymers with all classes of PFAS for "read across" or structure-activity relationship assessment is not scientifically appropriate.") See also footnote 244.

[254] For a more science-based, balanced approach to PFAS classification, see Guelfo, J. L.; Korzeniowski, S.; Mills, M. A.; Anderson, J.; Anderson, R. H.; Arblaster, J. A.; et al. Environmental Sources, Chemistry, Fate, and Transport of Per- and Polyfluoroalkyl Substances: State of the Science, Key Knowledge Gaps, and Recommendations Presented at the August 2019 SETAC Focus Topic Meeting. Environ. Toxicol. Chem. 2021, 40, 3234−3260 ("Outcomes illustrate that PFAS classification will continue to be a challenge, and additional pressing needs include increased availability of analytical standards and methods for assessment of PFAS and fate and transport, including precursor transformation.")

[255] Persistence and biodegradation can be hard to measure. See, for instance, Graham Whale, John Parsons, Kees van Ginkel, Russell Davenport, Eleni Vaiopoulou, Kathrin Fenner, Andreas Schaeffer, Improving our understanding of the environmental persistence of chemicals, Integr Environ Assess Manag 2021; 17:1123–1135, https://doi.org/10.1002/ieam.4438 ("Biodegradation tests have limitations, which are accentuated for "difficult-to-test" substances, and failure to recognize these can potentially lead to inappropriate conclusions regarding a chemical's environmental persistence."). Cf. Andreas Schäffer, Kathrin Fenner, Zhanyun Wang and Martin Scheringer, To be or not to be degraded: in defense of persistence assessment of chemicals, Environ.

Interestingly, they do not, and cannot, claim that the group of PFAS substances, as defined, shares a common hazardous property. Fluoropolymers, for example, are non-hazardous, biologically and chemically stable, immobile, and insoluble, many are regarded as polymers of low concern by the OECD and some fluoropolymers benefit from food contact approvals.[256] The common property of concern to the proponents is solely persistence of either the substance itself or its degradation products. Since PFAS with demonstrated degradability are not exempted, however, it is not clear on what basis the proponents concluded that persistence, in fact, is a common property of the entire group of PFAS substances.

5) US EPA working definition

Although the PFAS proposal discusses US legislative and regulatory initiatives on PFAS, it does not discuss the working definition of PFAS drafted by the US Environmental Protection Agency, maybe because the proponents did not want to delay their proposal. The US EPA definition differs significantly, however, from the definition included in the proposal.[257]

While the PFAS proposal covers over 10,000 substances, the US EPA definition includes 18 PFAS substances.[258] Of course, the two definitions have not been drafted for the same

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Sci.: Processes Impacts, 2022, 24, 1104-1109, DOI: 10.1039/D2EM00213B (" Persistence has been successfully characterized for readily and for slowly degradable chemicals using standardized tests, but for the third group of chemicals with intermediate degradability ("middle group"), the assessment is less straightforward.")

[256] OECD, JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY DATA ANALYSIS OF THE IDENTIFICATION OF CORRELATIONS BETWEEN POLYMER CHARACTERISTICS AND POTENTIAL FOR HEALTH OR ECOTOXICOLOGICAL CONCERN, ENV/JM/MONO(2009)1, Paris, 2009, https://www.oecd.org/env/ehs/risk-assessment/42081261.pdf Cf. Stephen H. Korzeniowski, Robert C. Buck, Robin M. Newkold, Ahmed El kassmi, Evan Laganis, et al., A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and Fluoroelastomers, Integrated Environmental Assessment and Management, 2022, Vol. 19, Nr. 2, pp. 326–354, https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4646?af=R Barbara J Henry, Joseph P Carlin, Jon A Hammerschmidt, Robert C Buck, L William Buxton, et al., A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers, Integrated Environmental Assessment and Management, Vol. 14, Nr. 3, pp. 316–334, https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4035 ("This paper brings together fluoropolymer toxicity data, human clinical data, and physical, chemical, thermal, and biological data for review and assessment to show that fluoropolymers satisfy widely accepted assessment criteria to be considered as "polymers of lowconcern" (PLC). This review concludes that fluoropolymers are distinctly different from other polymeric and nonpolymeric PFASand should be separated from them for hazard assessment or regulatory purposes. Grouping fluoropolymers with all classes of PFAS for "read across" or structure–activity relationship assessment is not scientifically appropriate.")

[257] "For the purpose of CCL 5, the structural definition of per- and polyfluoroalkyl substances (PFAS) includes chemicals that contain at least one of these three structures (except for PFOA and PFOS which are already in the regulatory process): (1) R-(CF2)-CF(R')R'', where both the CF2 and CF moieties are saturated carbons, and none of the R groups can be hydrogen; (2) R-CF2OCF2-R', where both the CF2 moieties are saturated carbons, and none of the R groups can be hydrogen; and (3) CF3C(CF3)RR', where all the carbons are saturated, and none of the R groups can be hydrogen." US Environmental Protection Agency, CCL 5 Chemical Contaminants, last updated Oct. 31, 2022, https://www.epa.gov/ccl/ccl-5-chemical-contaminants

[258] "In addition, 43 nominated chemicals consisting of 7 cyanotoxins, 18 DBPs, and 18 PFAS chemicals were included in the three chemical groups listed on the CCL 5 (i.e., the cyanotoxin, DBP, and PFAS groups)." ENVIRONMENTAL PROTECTION AGENCY, 40 CFR Part 141, Drinking Water Contaminant Candidate List 5—Final, Federal Register, Vol. 87, No. 218, Monday, Nov. 14, 2022, pp. 68060-68085.

purpose, but their scopes diverge to such an extent that it would be useful, if not necessary, to understand why the proponents of the PFAS proposal did not find the US EPA's definition appropriate for their purpose.

6) Circular reasoning

The reasoning of the proponents of the PFAS restriction to justify the use of this broad definition is circular. According to the draftsmen, it would be better to regulate PFAS as a group to avoid "regrettable substitution," but it is merely assumed, but not proven, that substitution will be regrettable, rather than desirable.

Not for a moment did the proponents of the PFAS restriction consider the realistic possibility that the overly broad restriction may well result in, rather than prevent, regrettable substitution; for example, where PFAS is critical to preventing accidents (e.g., where it used in various products that have a sealing and leak prevention function), substituting it with substances that have lower chemical and heat resistance, will increase environmental and safety risks.

The argument developed by the proponents effectively results in the circular, evidence-free argument that "PFAS are a group because they pose the same hazard, and PFAS share the same hazard because they are a group" and, therefore, they should be restricted 'en masse.'

ii. Grouping

In defending their grouping approach, the proponents do not pay any attention to ECHA's Read-Across Assessment Framework (RAAF), which sets forth "a framework and guidance for consistent evaluation of the scientific aspects of a proposed read-across case, resulting in an output which is suitable for subsequent regulatory consideration of the read-across case."[259] It would be too easy to conclude that the proponents are not interested in "consistent evaluation of the scientific aspects" of read-across and suitability for subsequent regulatory consideration" of their read-across case.[260]

[259] ECHA's Read-Across Assessment Framework (RAAF), March 2017, https://echa.europa.eu/documents/10162/13628/raaf_en.pdf/614e5d61-891d-4154-8a47-87efebd1851a Cf. OECD, GUIDANCE ON GROUPING OF CHEMICALS, SECOND EDITION, Series on Testing & Assessment, No. 194, 2017. T.W. Schultz, P. Amcoff, E. Berggren, F. Gautier, M. Klaric, D.J. Knight, C. Mahony, M. Schwarz, A. White, M.T.D. Cronin, A strategy for structuring and reporting a read-across prediction of toxicity, Regulatory Toxicology and Pharmacology, Volume 72, Issue 3, 2015, pp. 586-601, https://doi.org/10.1016/j.yrtph.2015.05.016, https://www.sciencedirect.com/science/article/pii/S0273230015001154

[260] "A read-across approach, either analogue or category approaches, is composed of elements addressing the structural similarity, a read-across hypothesis, a read-across justification and the prediction of property(ies) of the target substance(s)." ECHA's Read-Across Assessment Framework (RAAF), March 2017, p. 58.

1) Read-across assessment framework

On the other hand, it is understandable that the PFAS proposal is silent on ECHA's RAAF, because it is hard to see how the proposed PFAS grouping could be reconciled with the RAAF's assessment elements and assessment options, in particular, how the proposed grouping would fare against the standard of "adequacy and scientific robustness."[261]

Under REACH, ECHA's RAAF guidance explains, read-across must be justified by a set of criteria. The main criteria are the following:

- "any read-across approach must be based on structural similarity between the source and target substances;"
  - "However, structural similarity alone is not sufficient to justify the possibility to predict property(ies) of the target substance by read-across."
- "A read-across hypothesis needs to be provided."
  - "This hypothesis establishes why a prediction for a toxicological, ecotoxicological or environmental fate property is possible and should be based on recognition of the structural aspects the chemical structures have in common and the differences between the structures of the source and target substances."
- "The possibility for predictions of similar properties should be linked to the common structural aspects."
- "The differences in the chemical structures should not influence the toxicological, ecotoxicological or environmental fate properties or do so in a regular pattern."
- "The read-across approach must be justified scientifically and documented thoroughly, also taking into account the differences in the chemical structures."
  - "There may be several lines of supporting evidence used to justify the read-across hypothesis, with the aim of strengthening the case."[262]

The read-across framework described in ECHA's guidance considers "the simplest case of an analogue approach," i.e., read-across from a single source substance to a target substance, and warns that "[i]f an analogue approach uses more than one source or target substance, the assessment of the read-across approach has to be repeated for each source and/or target substance." Nothing in the PFAS proposal suggests that the proponents paid any attention to these criteria.

2) Relation to toxicology

The extremely broad definition of PFAS employed in the proposal serves to build a grouping approach that has no relationship with toxicology or with the grouping criteria under the REACH Regulation. It does not reflect toxicology, because the group of PFASs substances

[261] ECHA's Read-Across Assessment Framework (RAAF), March 2017, p. 15.
[262] ECHA's Read-Across Assessment Framework (RAAF), March 2017, https://echa.europa.eu/documents/10162/13628/raaf_en.pdf/614e5d61-891d-4154-8a47-87efebd1851a, p. 7.

includes many substances that have not been found to be hazardous[263] and even substances for which there is data affirmatively proving the absence of hazard in the required testing programs.[264]

The use of evidence relating to specific substances that fall within the scope of the broad PFAS definition to impute properties to other substances falling within that definition, is scientifically invalid because the conditions under which such read-across is reliable and justified have not been demonstrated to be present. On similar grounds, "[e]xperts generally agreed that use of a broad definition for PFAS (i.e., "all PFAS") should not be considered as a group for the purposes of risk assessment."[265]

3) PFAS grouping contrary to consensus

Indeed, in light of the findings of an expert group on the grouping of PFAS, the cavalier manner in which the proponents have gone about defining and grouping PFAS for purposes

[263] "The OECD definition of PFASs is based on chemical structure. Hazardous properties or risks are not part of it. The substance scope of the proposed restriction is additionally a concern based one as it intends to cover PFASs that are very persistent, with the aim to address the concerns associated with the persistent nature of these substances." PFAS Proposal, p. 19.

[264] Examples include the "fourth generation" hydrofluoroolefins (HFOs), such as HFO-1234ze(E), and fluoropolymers such as polychlorotrifluoroethylene (PCTFE). HFO-1234ze(E) is non-persistent (not P or vP), does not degrade to persistent substances (except to an insignificant degree), and does not have properties similar to PBT/vPvB substances, or raise the concerns addressed by the PFAS proposal. PFAS Proposal, Section 1.1.4. Hazard assessment. HFO-1234ze(E) is approved for use in medical pressurised meter dose Inhalers (pMDI). See further ECHA, HFO-1234ze(E), https://echa.europa.eu/nl/registration-dossier/-/registered-dossier/31292 PCTFE is a non-hazardous polymer of low concern and has been approved for use in medicinal and medical devices packaging. See, for instance, EMA, https://www.ema.europa.eu/en/documents/all-authorised-presentations/spedra-epar-all-authorised-presentations_nl.pdf

[265] "Experts generally agreed that use of a broad definition for PFAS (i.e., "all PFAS") should not be considered as a group for the purposes of risk assessment." Cf. Anderson JK, Brecher RW, Cousins IT, DeWitt J, Fiedler H, Kannan K, Kirman CR, Lipscomb J, Priestly B, Schoeny R, Seed J, Verner M, Hays SM. Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts. Regul Toxicol Pharmacol. 2022 Oct;134:105226. doi: 10.1016/j.yrtph.2022.105226. Epub 2022 Jul 8. PMID: 35817206. "PFAS are by no means a monolithic class of chemicals. They can be per- or polyfluorinated, straight or branched chained, and contain alkyl chains of varying lengths. PFAS may also contain ether linkages and either sulfonic acid or carboxylic acid R-group moieties. … Collectively, these data raise two important points. First, sulfonic acid aliphatic PFAS can be grouped based on their ability to cause the same morphological and behavioral toxicity phenotypes in zebrafish (i.e., failed swim bladder inflation, abnormal ventroflexion of the tail, and, at nonteratogenic concentrations, hyperactivity). Second, although carbon chain length generally increases PFAS potency, this dogma cannot be universally applied to all structurally similar PFAS, as exceptions to the rule exist (i.e., PFPeS). … Future research should consider testing groups of related PFAS in environmentally relevant mixtures. … We specifically identified aliphatic sulfonic acid PFAS as a particularly bioactive class of PFAS, thereby identifying relationships between chemical structures and in vivo phenotypes that may arise from putative shared mechanisms of PFAS toxicity. … These data show that this emerging PFAS, in addition to other branched and/or fluoroether PFAS examined here, is negative for developmental toxicity and developmental neurotoxicity in zebrafish, possibly identifying a less bioactive group of PFAS (at least in the context of fish toxicology)." Gaballah S, Swank A, Sobus JR, Howey XM, Schmid J, Catron T, McCord J, Hines E, Strynar M, Tal T. Evaluation of Developmental Toxicity, Developmental Neurotoxicity, and Tissue Dose in Zebrafish Exposed to GenX and Other PFAS. Environ Health Perspect. 2020 Apr;128(4):47005. doi: 10.1289/EHP5843. Epub 2020 Apr 9. PMID: 32271623; PMCID: PMC7228129.

of imposing bans is quite irresponsible. The basic propositions set forth in the PFAS proposal contradict all key findings of this expert group:

> "Most experts agreed that "all PFAS" should not be grouped together, persistence alone is not sufficient for grouping PFAS for the purposes of assessing human health risk, and that the definition of appropriate subgroups can only be defined on a case-by-case manner. Most panelists agreed that it is inappropriate to assume equal toxicity/potency across the diverse class of PFAS. A tiered approach combining multiple lines of evidence was presented as a possible viable means for addressing PFAS that lack analytical and/or toxicological studies."[266]

Unlike the proponents, the UK Health and Safety Executive (HSE) appears to have taken these recommendations to heart, and concluded that "[t]here are a number of challenges and shortcomings associated with using a structural grouping approach for PFAS."[267] A generic PFAS definition is regarded as "not particularly useful from a regulatory perspective." Instead of the "all PFAS" approach, the HSE recommends the adoption of "regulatory approaches on the basis of particular PFAS groups and/or uses."[268]

4) PFAS grouping contrary to law

Further, the proposed grouping violates of the principles underlying and enshrined in the REACH Regulation, such as the substance-by-substance approach, which is the default model for regulating chemical risk (also in the context of the restrictions procedure[269]), and the grouping and read-across methodologies. The grouping used for the PFAS restriction does not identify the substances to be restricted and is inconsistent with the principle of substance-specific regulation enshrined in the REACH Regulation, as it incorrectly assumes that the REACH Regulation authorizes regulation based merely on a molecular configuration[270] common to a large, open-ended group of substances.

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[266] Anderson JK, Brecher RW, Cousins IT, DeWitt J, Fiedler H, Kannan K, Kirman CR, Lipscomb J, Priestly B, Schoeny R, Seed J, Verner M, Hays SM. Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts. Regul Toxicol Pharmacol. 2022 Oct;134:105226. doi: 10.1016/j.yrtph.2022.105226. Epub 2022 Jul 8. PMID: 35817206.

[267] UK HSE, Analysis of the most appropriate regulatory management options (RMOA): Poly- and perfluoroalkyl substances (PFAS), March 2023, https://www.hse.gov.uk/reach/assets/docs/pfas-rmoa.pdf , p. 14.

[268] UK HSE, Analysis of the most appropriate regulatory management options (RMOA): Poly- and perfluoroalkyl substances (PFAS), March 2023, https://www.hse.gov.uk/reach/assets/docs/pfas-rmoa.pdf , p. 21.

[269] The REACH Regulation requires that a substance to be restricted is identified. It requires, for instance, that a dossier "shall include the identity of the substance." Section 3, Annex XV, REACH Regulation. Likewise, ECHA's Guidance on Annex XV dossiers stipulates that such a dossier should include "details on the identity of the substance (substance name, CAS/EC number(s)), registration number(s) (if available), molecular formula, structural formula, purity and impurities)." ECHA, Guidance for the preparation of an Annex XV dossier for restrictions, 2007, https://echa.europa.eu/documents/10162/2324906/restriction_en.pdf/d48a00bf-cd8d-4575-8acc-c1bbe9f9c3f6, p. 108.

[270] This configuration is "any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it."

This assumption is unjustifiable and inconsistent with the REACH Regulation. The European Commission has proposed that the idea of "one substance, one assessment" be implemented throughout EU chemical policies, but the PFAS proposal perverts this concept into "one assessment, many substances."

The grouping approach employed by the proponents, which lumps together fluoropolymers, fluoromonomers, fluorinated gases, and non-existent PFAS, breaches the REACH criteria for grouping and read-across. The data, hazard and risk assessment for some substances cannot be read-across to other substances that are covered by the PFAS proposal, since the criteria for read-across are not met. The PFAS proposal repeatedly refers to the "persistence" of all PFAS substances and thus appears to have employed a concept of "hazard" that conflicts with the REACH Regulation's standards for hazard; persistence, without more, is not a hazard. Moreover, the hazard assessment employed by the proponents violates the REACH Regulation due to, inter alia, the use of extraneous criteria and unjustifiable extra- and interpolation to all substances falling within the scope. For the vast majority of substances covered by the PFAS Proposal, no hazardous properties as defined by REACH and the CLP Regulation have been established. Under EU chemical law, "classification and labelling based on risk are linked to specific use and specific conditions of exposure."[271]

5) Grouping of hazardous and non-hazardous substances

Moreover, the vast majority of the substances covered by the PFAS Proposal are not classified as hazardous and do not meet the criteria to be considered either PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative). PBT assessment requires that toxicity be established for the substance concerned. Without toxicity, there can be no hazard resulting from PBT classification. vPvB classification requires that substances be both very persistent and very bioaccumulative pursuant to the criteria defined in the REACH Regulation and CLP Regulation. PBT and vPvB assessments are to be conducted based on the criteria set forth in Annex XIII of the REACH Regulation. For the identification of PBT substances and vPvB substances "a weight-of-evidence determination using expert judgement" is to be applied. For many PFAS substances for which such assessments have been conducted, no PBT or vPvB classification applies or no PBT/vPvB assessment as required by the REACH Regulation have been done. There thus is no basis in science for the assumption that all of these PFAS substances would be PBT or vPvB.

6) Extrapolation and association

In an attempt to impute hazard to the entire group of PFAS substances, the proponents employ extrapolation and association. In addition to persistence, which allegedly would apply to the entire group but is not a hazardous property, the PFAS proposal refers to

[271] Opinion AG Bot, Case C-15/10, Étimine SA v Secretary of State for Work and Pensions, 24 March 2011.

properties[272] such as bioconcentration, bioaccumulation,[273] mobility,[274] long-distance transport,[275] and human health effects,[276] but these properties apply only to one or more specific PFAS substances or to some classes or subgroups, not to the entire group.

This substance- or subgroup-specific evidence requires further evaluation, but in no event can it support extrapolation to the entire group of PFAS substances. The only hard conclusion is that the proponents have not been able to establish a common hazardous property for the group of PFAS, as defined, which is a prerequisite for restricting PFAS as a group.

7) Lack of evidence

Throughout their Annex XV dossier, the proponents show that they know they do not have the evidence to support their grouping proposal. For instance, they acknowledge that "for most PFASs there are insufficient data to adequately assess their effects on human health and the environment."[277] Further, they admit that "studies on accumulation of PFASs in plants are lacking for the majority of PFASs,"[278] and that "for the majority of PFASs no, or insufficient, data on bioaccumulation behaviour are available."[279]

With respect to ecotoxicity, they merely lament that "[t]he large number of different substances with heterogenous properties (e.g. due to different functional groups) in the group of PFASs makes the assessment of their ecotoxicity very complex."[280] In the end, they concede that "[d]ue to the high diversity of the PFASs the bioaccumulation potential and ecotoxicity/toxicity are expected to vary among the substances," and "no overall conclusion on B/vB and T criteria was derived for each PFAS substance/(sub-)group."[281]

8) Moral appeal

The proponents therefore appeal not to the strength of the evidence, but to the morality of the decision-makers. As "increasing research efforts that progressed beyond PFOS and PFOA

[272] "Further supporting concerns are their bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects." PFAS Proposal, p. 1.
[273] In some cases, the proponents have to simultaneously relativize their statements so as to not be accused of misrepresentation. See, for instance: "Available laboratory bioconcentration studies in freshwater fish indicate that PFASs with a shorter alkyl chain, i.e. HFPO-DA, EEA-NTH, ADONA, are generally less bioaccumulative in fish." PFAS Proposal, p. 27.
[274] "Most PFASs, including persistent PFAS metabolites, are either mobile in water or accumulate in biota, and both lead to unavoidable exposure of humans and the environment." PFAS Proposal, p. 13.
[275] "The high mobility of certain (groups of) PFASs allows for long-distance transport via air or surface water and ground water on a global scale." PFAS Proposal, p. 38.
[276] "Although for most PFASs there are insufficient data to adequately assess their effects on human health and the environment, increasing research efforts that progressed beyond PFOS and PFOA reported similar adverse effects for other PFASs." PFAS Proposal, p. 13.
[277] PFAS Proposal, p. 13.
[278] PFAS Proposal, p. 26.
[279] PFAS Proposal, p. 28.
[280] PFAS Proposal, p. 28.
[281] PFAS Proposal, p. 47.

reported similar adverse effects for other PFASs,"[282] the proponents suggest that the regulators should set aside the legal requirements to prevent possible future harms.

The only rational and lawful response from the regulators can be "come back when you have the scientific evidence. "Science-based chemical regulation is incompatible with a moralistic approach that proceeds on the basis of mere presumptions.

9) Assessment of regulatory needs

Another clear indication that the grouping embodied in the PFAS proposal contradicts the REACH Regulation is provided by ECHA's Assessment of Regulatory Needs (ARN) process. In fact, the proponents appear to have adopted the grouping methodology described by ECHA for purposes of extra-legal, unregulated ARN procedure. Pursuant to this method, grouping is based on "structural similarity, which uses the substance identity information in registration dossiers and C&L notifications; and associations made by the registrants between substances through read-across and category approaches as well as category associations from external sources (e.g., OECD categories)."[283]

Specifically, structurally similar substances are identified "within the universe of registered substances around pre-selected substances known as 'seeds',[284]" for instance, substances known to be hazardous such as PFOS and PFOA. Although ECHA found the Annex XV dossier for the PFAS restriction compliant with the REACH Regulation's formal requirements,[285] it admits that these grouping methods are not appropriate for regulatory procedures under the REACH Regulation, since they differ "from grouping as defined in Section 1.5 of Annex XI to REACH and therefore do not constitute validated read-across and category information."[286] Likewise, as discussed above, the grouping of all PFAS for restriction does not meet the REACH Regulation's requirements and does not constitute validated read-across and category information.

[282] PFAS Proposal, p. 13.
[283] ECHA, Questions and Answers, Assessment of Regulatory Needs, How is the grouping done by ECHA?, No. 1868, 10/12/2021, https://echa.europa.eu/support/qas
[284] "Examples of seeds are substances in Annex VI to the CLP Regulation, in the Candidate List or listed in the CoRAP, for which there is already an identified or potential hazard. Another starting point for grouping could be a substance that has a certain type of use or function with a potential for exposure." ECHA, Questions and Answers, Assessment of Regulatory Needs, How is the grouping done by ECHA?, No. 1868, 10/12/2021, https://echa.europa.eu/support/qas
[285] "The Committee for Risk Assessment and the Committee for Socio-economic Analysis shall check whether the dossier submitted conforms to the requirements of Annex XV." Article 69(4), REACH Regulation.
[286] Natsch et al. have shown that the groupings for purposes of ARN do not take into consideration "mode of action and the toxicological information on the chemicals," as a result of which "the groupings in the ARN set an unfortunate precedent on what a toxicological group means and they do not follow clear scientific standards or established toxicological principles." Natsch, A., Adamsson, G. & Rocha, V. ECHA ARN documents: chemical grouping without a toxicological rationale. Arch Toxicol 97, 1433–1437 (2023), https://doi.org/10.1007/s00204-023-03479-3

10) Fixing overly broad grouping through exemptions

The "remedy" proposed by the proponents, i.e. granting derogations, does not cure the fundamental deficiency of the overly broad PFAS definition and related grouping and inappropriately (and unlawfully) reverses the burden of proof. It reverses the burden of proof in breach of the principle that in both regulatory science and chemical risk regulation risk must be demonstrated; negative proof of the absence of any risk is not required. In other words, based on data submitted by the industry (or other reliable data), the regulators must demonstrate risk.

The proponents of the PFAS restriction have failed to demonstrate risk for most of the substances they plan to bring within the scope of their proposal. As discussed further below,[287] the "derogation-carrot" they decided to hang out is not only unlawful, but also serves to place the burden of proof on companies and extract information from them that can justify further regulation.

iii. Persistence as Harm

The alleged persistence of all PFASs substances serves as proxy for harm, or probable harm or a significant risk of harm. Harm, in this view, results from several causes that are not directly related to any known toxic properties of all PFAS substances. First, harm results from "the regrettable substitution seen in the case of long-chain PFASs."[288] Second, harm results from the very high number of PFASs on the market, which would show that "the approach taken until now of regulating them individually (or in small groups of closely related substances) is not efficient and does not fully address the concerns they pose."[289]

1) Presumed harm

The argument proffered by the proponents, of course, is not an argument about harm at all. It is a presumption of harm that is disguised as a different way of saying that the REACH Regulation requires substance-by-substance regulation, subject to limited exceptions for grouping.

These conceptualizations of harm are not recognized as harms that can ground regulation under the REACH Regulation. They are mere invitations to policy makers to endorse the ideal of "toxic-free" society.

2) Combined effects

According to the proponents of the PFAS restriction, harm would also result from the combined effects of PFAS substances. Specifically, "[w]idespread use of multiple substances from the PFASs group increases the risk of combined effects from PFASs." Their proposal therefore "addresses them as a group." An approach to grouping "based on persistence

[287] See section 3.b.iv. below.
[288] PFAS Proposal, pp. 68-69.
[289] PFAS Proposal, pp. 68-69.

alone" is deemed justified because "the continuous release of persistent chemicals will lead to widespread, long-lasting, irreversible and increasing contamination."

There is only scant evidence of such combined effects, however. While there is some evidence of possible adverse combined effects of specific PFAS substances, there is no evidence of adverse combined effects for many PFAS substances falling within the scope of the proposed restriction. Maybe the proponents could justify their approach for those substances for which they have evidence of combined effects. To proceed with a broad ban on the basis of presumed combined effects, however, is not consistent with the EU's chemical risk regulatory framework.

3) Preventing contamination

The real harm that is targeted by the proposed PFAS restriction is "contamination" as such. Contamination without adverse effects, however, raises issues that cannot be addressed within the context of restriction under the REACH Regulation.

Unlike the industrial emissions and environmental quality legislation, the REACH Regulation is not a regulatory program that addresses contamination as such; it is designed to regulate chemical risk, which in the case of restrictions requires a showing of "unacceptable risk." Insofar as the proponents appeal to a need to minimize PFAS contamination, they should not push for a REACH restriction but submit a legislative proposal to amend the EU's environmental legislation.

4) Unknowable future harm

A closely related argument, the proponents go on to argue that continuing releases of PFAS "will also result in increasing probabilities of adverse effects on human health and the environment."[290] Evidence of such increasing probabilities is not provided, however; the statement is based on the assumption that "[c]ontinued emissions of PFASs (including from the end-of-life phase of products) will result in an increasing environmental stock and, hence, increasing exposures," which, in turn, would result in "a high likelihood that known thresholds of PFASs to cause adverse effects – as well as yet unknown thresholds - are exceeded."[291]

While this, in theory (and depending on release control and exposure prevention measures), may be true for some PFAS substances, it is merely an assumption for the vast majority of

[290] Annex XV Restriction Report, PFASs, 22 March 2023, p. 68-69.
[291] PFAS Proposal, p. 48. The proponents appear to have borrowed this argument from Scheringer. See Scheringer M., Johansson J.H., Salter M.E., Sha B., and Cousins I.T., Stories of Global Chemical Pollution: Will We Ever Understand Environmental Persistence? Environ. Sci. Technol. 2022, 56, 24, 17498–17501., DOI: 10.1021/acs.est.2c06611. ("Regardless of their physicochemical properties, the continuous release of PFAS will lead to their accumulation somewhere in the environment until some known or unknown effect threshold is exceeded.")

PFAS substances.[292] There may be no thresholds, because PFAS substances may not be toxic, for instance.

5) Presumed impossibility of exposure prevention

The PFAS Proposal lumps together all sort of substances irrespective of whether and, if so, how, actual exposure occurs in individual cases. Furthermore, it advocates for a broad definition in the absence of persuasive evidence that release of PFAS at various stages of production and use cannot be controlled better.

Upon close analysis, it becomes apparent that the reasoning of the proponents does not apply to any PFAS substances that are not toxic and any uses that can be managed better in terms of PFAS release. All these substances and uses are covered only because they share a common molecular configuration.

6) The definition of hazard

As discussed in Section 3.a.iii, above, the REACH Regulation does not treat persistence, without more, as a hazard, let alone, a risk or even an "unacceptable risk." Only PBT and vPvB are hazardous properties. Merely vP, without vB, is not a hazardous property.

There are good reasons for not treating P or vP, without more, as a hazard.[293] As the REACH Regulation stipulated, "a substance that fulfils the persistence and bioacumulation criteria shall be considered to be a vPvB substance,"[294] not any other substance. The Delegated Act under the CLP Regulation,[295] which formalizes the PBT and vPvB classification, does not change this. Persistence on its own is not a hazard; it is only considered in connection with bioaccumulation and toxicity. A substance that is persistent, but not bioaccumulative or toxic, cannot be hazardous.

7) PBT/vPvB assessment

A PBT or vPvB assessment can only be done on a specific substance; it cannot be done on a group of substances as broadly defined and as varying as PFAS. Further, no argument is

[292] Cf. Georgia M. Sinclair, Sara M. Long, Oliver A.H. Jones, What are the effects of PFAS exposure at environmentally relevant concentrations?, Chemosphere, Volume 258, 2020, 127340, ISSN 0045-6535, https://doi.org/10.1016/j.chemosphere.2020.127340 ("Most PFAS detected in the environment were found to have a HQ risk value of <1 meaning their reported concentrations are below their predicted no effect concentration. This indicates many reported toxic effects of PFAS are, theoretically, unlikely to occur outside the laboratory.")
[293] Cf. ECHA, Guidance on Information Requirements and Chemical Safety Assessment -- Part C: PBT/vPvB assessment, Version 3.0, June 2017, https://echa.europa.eu/documents/10162/13643/information_requirements_part_c_en.pdf
[294] Annex XIII, REACH Regulation.
[295] COMMISSION DELEGATED REGULATION (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures, OJ L 93/7, 31.3.2023.

made that any PBT or vPvB hazard of any PFAS meets the criteria for read-across to the entire group, so that it can be imputed to all other PFAS falling within the scope of the PFAS Proposal.

As the proponents cannot even establish PBT/vPvB hazards for the substances subject to their bans, they have failed *a priori* to provide "scientific evidence of probable serious effects to human health or the environment" equivalent to the hazards/risks covered by the REACH Regulation. Accordingly, the proponents have failed to demonstrate that the vast majority of PFAS covered by the PFAS proposal are hazardous or pose "unacceptable risk."

8) Persistence alone

Based on wishful thinking and flawed reasoning, the proponents of the PFAS proposal attempt to rewrite the REACH Regulation to suggest that "persistence alone" should be deemed sufficient to justify restrictions. Under the rule of law, however, a political drive to speed up the regulation of substances that are in the spotlight does not set aside the existing law.

To make up for this weakness of their proposal, the proponents invoke the authority of scientists who have argued in favor of expanding regulation to cover persistent chemicals such as PFAS. Indeed, to support the idea of treating persistence on its own as harm the proponents were able to refer to some toxicological literature, which argues in favor of doing so.[296] The references provided by the proponents of the PFAS ban are to several authors that have been vocal about PFAS and advocate for PFAS regulation based on persistence.[297]

Their argument is that high environmental persistence should be "a core element of responsible chemicals management," in support of which they refer to cases in which persistent substances later on turned out to be harmful.[298] Cases in which persistent substances do not cause any harm, however, are ignored or downplayed.

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[296] "This grouping approach is acknowledged as a basis for risk assessment also by several scientists, who consider that regulation of PFASs on the basis of persistence alone should already suffice (see e.g. Cousins et al. (2020b); Scheringer et al. (2022))." The two publications to which reference is made are Cousins I.T., DeWitt J.C., Gluge J., Goldenman G., Herzke D., Lohmann R., Ng C.A., Scheringer M., and Wang Z., The high persistence of PFAS is sufficient for their management as a chemical class. Environmental science. Processes & impacts, 2020, 22 (12), 2307-2312. DOI: 10.1039/d0em00355g. Scheringer M., Johansson J.H., Salter M.E., Sha B., and Cousins I.T., Stories of Global Chemical Pollution: Will We Ever Understand Environmental Persistence? Environ. Sci. Technol. 2022, 56, 24, 17498–17501., DOI: 10.1021/acs.est.2c06611. The latter paper refers back to the first paper.

[297] These authors have recycled the same argument in various publications. See, for instance, Cousins, I. T.; Johansson, J. H.; Salter, M. E.; Sha, B.; Scheringer, M. Outside the Safe Operating Space of a New Planetary Boundary for Per- and Polyfluoroalkyl Substances (PFAS). Environ. Sci. Technol. 2022, 56, 11172– 11179, DOI:10.1021/acs.est.2c02765. Schäffer, A.; Fenner, K.; Wang, Z.; Scheringer, M. To be or not to be degraded: in defense of persistence assessment of chemicals. Environ. Sci.: Processes Impacts 2022, 24, 1104– 1109, DOI:10.1039/D2EM00213B. Cousins, I. T.; Ng, C. A.; Wang, Z.; Scheringer, M. Why is High Persistence Alone a Major Cause of Concern?. Environ. Sci. Process. Impacts 2019, 21, 781– 792, DOI: 10.1039/C8EM00515J

[298] Scheringer M., Johansson J.H., Salter M.E., Sha B., and Cousins I.T., Stories of Global Chemical Pollution: Will We Ever Understand Environmental Persistence? Environ. Sci. Technol. 2022, 56, 24, 17498–17501., DOI:

9) False negatives versus false positives

A bias in favor of false negatives while ignoring all false positives is typical for lobsided precautionary reasoning.[299] The repeated pleas for regulation based on persistence without more originate from a small group of vocal scientists, however, and are not representative of science as such.

In line with the bias in favor of false negatives, the PFAS proposal selectively refers to scientists that advocate for a regulating PFAS based on persistence alone and omit references to scientists that disagree with this recommendation.[300]

10) Confusing science and policy

More importantly, the so-called "persistence-sufficient approach" advocated by scientists such as Cousins and Scheringer[301] is not a scientific conclusion, but a policy position. The

10.1021/acs.est.2c06611. ("We conclude that regulation of chemicals has been focused too much on adverse effects alone and that this focus has diverted regulatory attention from persistence as the underlying driver of the unfolding global problems. We further conclude that it is necessary to develop chemicals regulation that addresses high persistence alone.")

[299] Cousins, I. T.; Ng, C. A.; Wang, Z.; Scheringer, M. Why is High Persistence Alone a Major Cause of Concern?. Environ. Sci. Process. Impacts 2019, 21, 781– 792, DOI: 10.1039/C8EM00515J ("Regulation of highly persistent chemicals, for example by restriction of emissions, would not only be precautionary, but would serve to prevent poorly reversible future impacts.") Stephenson, M. S. An Approach to the Identification of Organic Compounds Hazardous to the Environment and Human Health. Ecotoxicol. Environ. Safety 1977, 1, 39– 48, DOI: 10.1016/0147-6513(77)90016-1 ("Materials which are strongly persistent can accumulate to rather high levels in the environment and effects which would not otherwise be important could become so".) Cousins, I. T., Ng, C. A., Wang, Z., & Scheringer, M., Why is high persistence alone a major cause of concern? Environmental Science: Processes & Impacts, 2019, 21, 781–792. https://doi.org/10.1039/c8em00515j ("We demonstrate that if a chemical is highly persistent, its continuous release will lead to continuously increasing contamination irrespective of the chemical's physico-chemical properties. We argue that these increasing concentrations will result in increasing probabilities of the occurrence of known and unknown effects and that, once adverse effects are identified.")

[300] See, for instance, Anderson JK, Brecher RW, Cousins IT, DeWitt J, Fiedler H, Kannan K, Kirman CR, Lipscomb J, Priestly B, Schoeny R, Seed J, Verner M, Hays SM. Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts. Regul Toxicol Pharmacol. 2022 Oct;134:105226. doi: 10.1016/j.yrtph.2022.105226. Epub 2022 Jul 8. PMID: 35817206. Cf. Bruno Ameduri, Fluoropolymers: A special class of per- and polyfluoroalkyl substances (PFASs) essential for our daily life. Journal of Fluorine Chemistry 2023, 267 , 110117, https://doi.org/10.1016/j.jfluchem.2023.110117 (arguing that fluoropolymers are persistent but not hazardous). Cf. Mackay, Don, Lynn S. McCarty, and Matthew MacLeod. On the validity of classifying chemicals for persistence, bioaccumulation, toxicity, and potential for long-range transport, Environmental Toxicology and Chemistry: An International Journal 20.7 (2001): 1491-1498. ("It is argued that chemical substances can be meaningfully ranked or classified according to their persistence (P), bioaccumulation (B), toxicity (T), and potential for long-range transport (LRT) only if these attributes can be shown to be intensive, as distinct from extensive, properties of the substance, i.e., they are independent of quantity of substance. It is shown that P, B, and LRT can be considered intensive or quasi-intensive properties, but toxicity is more problematic.")

[301] Cousins, I. T., Ng, C. A., Wang, Z., & Scheringer, M., Why is high persistence alone a major cause of concern? Environmental Science: Processes & Impacts, 2019, 21, 781–792. https://doi.org/10.1039/c8em00515j

issue these scientists address, namely, on what basis should chemicals be regulated, is not a scientific issue – it is a policy and political issue that belongs to the domain of policymaking, not science.[302]

Rather than providing support for the proposed PFAS ban the references to the publication of these scientists raise questions about the objectivity of their scientific work: are scientists who take strong policy positions biased in the scientific work that relates directly to their policy positions? After all, it would be very useful if science were to support the policy position.[303]

11) Durability portrayed as persistence

There is a deeper philosophical issue associated with treating persistence as a hazard. In many cases, what is referred to as 'persistence' is a useful and desirable property. Persistence is merely a pejorative way of referring to desirable properties such as durability and sustainability. For instance, pipes, drains and seals that contain PFAS prevent accidents, save lives, and result in maintenance cost savings.[304] Silica[305] and steel[306] are, fortunately, very persistent in the environment.

The persistence of these materials is their strength and provides very substantial benefits to mankind. The PFAS proposal, however, makes no attempt to understand these benefits, frames durability as "persistence," and then positions persistence as a necessarily undesirable property that will cause mischief.

12) PFAS and alternatives

In some cases, the proponents are able to refer to alternative substances that, to some extent, can serve the same functions as the PFAS substances they should replace, but in

[302] Cf. Matthies, Michael, Solomon, Keith, Vighi, Marco, Gilman, Andy, Tarazona, Jose V., The origin and evolution of assessment criteria for persistent, bioaccumulative and toxic (PBT) chemicals and persistent organic pollutants (POPs), Environmental Science: Processes & Impacts, 2016, pp. 1114 – 1128, http://dx.doi.org/10.1039/C6EM00311G ("Criteria are not defined purely by science; they also are subject to the aims of policy.")

[303] Cousins has also taken strong positions on the concept of essential use as a way to phase out PFAS. Ian T. Cousins et al., Finding essentiality feasible: common questions and misinterpretations concerning the "essential-use" concept. Environ. Sci.: Processes Impacts, 2021,23, 1079-1087. Cousins, I.T.; Goldenman, G.; Herzke, D.; Lohmann, R.; Miller, M.; Ng, C. A.; et al., The concept of essential use for determining when uses of PFASs can be phased out, Environ. Sci.: Processes Impacts, 2019,21, 1803-1815, https://doi.org/10.1039/C9EM00163H ("To determine when uses of PFASs have an essential function in modern society, and when they do not, is not an easy task.")

[304] There is no assurance that non-PFAS alternatives are available in all such applications and no guarantee that they would perform as well PFAS.

[305] Ballmer, M., Houser, C., Hernlund, J. et al. Persistence of strong silica-enriched domains in the Earth's lower mantle. Nature Geosci 10, 236–240 (2017). https://doi.org/10.1038/ngeo2898

[306] V.K. Bupesh Raja, K. Palanikumar, R. Rohith Renish, A.N. Ganesh Babu, Jashwanth Varma, P. Gopal, Corrosion resistance of corten steel – A review, Materials Today: Proceedings, Volume 46, Part 9, 2021, pp. 3572-3577, https://doi.org/10.1016/j.matpr.2021.01.334, https://www.sciencedirect.com/science/article/pii/S2214785321004259

many cases such evidence is lacking. In all cases, there is no evidence whatsoever that alternative substances pose lower risks and provide the same benefits.

Obviously, there are good reasons as to why PFAS substances have become very successful commercial products. These reasons have to do with their unsurpassed performance in many applications, and this unsurpassed performance is a function of their persistence. PFAS product restriction will likely have substantial negative consequences for the performance of many products. If only uses deemed "essential" by regulators will be permitted, the social losses will likely be substantial. These losses have not been estimated by the proponents of the PFAS restriction, however.

iv. Emissions as a proxy for risk

In the methodology adopted by the proponents, based on the presumed non-threshold nature of all PFAS substances, emissions are deemed to be a proxy for exposure and for risk. Their proposition is that continuing emissions will increase the "pollution stock" in the environment and lead to "a growing risk of negative environmental and health impacts and, thus, damages over time."[307]

Restricting emissions in the EU would reduce these risks. However, the PFAS proposal does not consider the risk that EU restrictions may result in increased PFAS manufacturing and use outside the EU and merely move emissions to outside the EU, not reduce global emissions.

1) Conditions for emissions to equate harm

Setting this issue aside, even if the EU is treated as an island, once the causal argument of the proponents is unpacked and scrutinized, the treatment of emissions as a proxy for risk for the entire group of PFAS substances becomes doubtful. Each link in the causal chain raises issues that undermine the general application of the assumptions made.

In order to be able to make a valid projection of a risk of harm, a reference to emissions of persistent PFAS is insufficient. Not only does it need to be shown that all PFAS covered by the proposed restriction are very persistent and very bioaccumulative, it also needs to be demonstrated that predicted environmental concentrations are likely to exceed safe levels. There is no reason to assume that large, biologically and chemically stable PFAS molecules that do not pass cell membranes are a cause for concern, even if they are persistent. Furthermore, for no no-effect levels have been established for PFAS,[308] and there, a priori, is no evidence that any such levels are exceeded.

[307] PFAS Proposal, p. 49.
[308] "Information to derive a robust predicted no effect concentration (PNEC) as well as a predicted environmental concentration (PEC) is currently insufficient." PFAS Proposal, p. 190.

2) *Lack of rigor in emission estimates*

The lack of rigor in estimating PFAS emission rates, resulting exposure and associated potential risks is evident in the way the PFAS proposal treats fluorinated gases (F-gases) and fluoropolymers.[309] F-gases are included within the scope of the restriction because they not only contribute to global warming,[310] but also are potential precursors to trifluoroacetic acid (TFA).[311]

The proponents argue that "as most of these substances[312] are expected to ultimately degrade in the environment to TFA, they will contribute to the overall exposure to and risks of PFAAs."[313] This incomplete, suggestive statement is inconsistent with scientific assessments of TFA, however. The proponents have grossly overestimated the rate at which F-gases degrade to TFA, because they have failed to consider the best available science, which projects rates many times lower.[314]

3) *Lack of rigor in harm assessments*

Further, a recent UNEP assessment concluded that TFA "has biological properties that differ significantly from the longer chain polyfluoroalkyl substances (PFAS) and inclusion of TFA in this larger group of chemicals for regulation would be inconsistent with the risk assessment of TFA."[315]

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[309] See further Section 2.c, above.

[310] "Some PFASs are gases. Once released, these PFASs are distributed around the globe where they contribute substantially to global warming and climate change." PFAS Proposal, p. 13. The PFAS Proposal omits the nuances, however: "One source of TFA in the environment is the degradation of replacements for chemicals that contribute to the destruction of stratospheric O3. These are the HCFCs, HFCs, and HFOs, all of which are replacements for chemicals that fall under the purview of the Montreal Protocol. Some of these products are greenhouse gases and contribute to global climate change. Because of this, there is a trend to replace long-lived HCFCs and HFCs with HFOs, which have very short atmospheric lifespans and do not contribute to climate change." UNEP Environmental Effects Assessment Panel, 2022 Assessment Report of the Environmental Effects, Montreal Protocol on Substances that Deplete the Ozone Layer, UNEP Nairobi, Ozone Secretariat, March 2023, http://ozone.unep.org/science/eeap, p. 292.

[311] "Some substances contain only a single –CF3 group attached to carbon, and because of their structure they are potential precursors to trifluoroacetic acid (TFA). To this subgroup belong, amongst others, some fluorinated gases and active ingredients in biocides, plant protection products and pharmaceuticals containing a -CF3 group bound to an aromatic ring. Fluorinated gases fulfilling the scope definition form the largest contribution by production volume to this subgroup." PFAS Proposal, p. 15.

[312] "Many PFASs contain only a single –CF3 group and are considered potential TFA precursors as a special subclass of PFAAs. This group is heterogeneous with various types of effects and mechanisms of actions. The effects of these substances measurable in standard tests can often be attributed to the non-fluorinated parts of the substances." PFAS Proposal, p. 15.

[313] PFAA is perfluoroalkyl acid. PFAAs are "stable metabolites or 'arrowheads'." PFAS Proposal, p. 15.

[314] A World Meteorological Organization scientific assessment found that "if there is a hydrogen on the central carbon atom there is no TFA formation, such as in CF3CH=CHF (HFO-1234ze) or CF3CH=CHCl (trans-1-chloro-3,3,3-trifluoropropylene or tCFP; also referred to as HFO-1233zd)." World Meteorological Organization (WMO), Scientific Assessment of Ozone Depletion: 2014, World Meteorological Organization, Global Ozone Research and Monitoring Project—Report No. 55, Geneva, Switzerland, 2014, Chapter 5, section 5.2.5, p. 5.11, https://csl.noaa.gov/assessments/ozone/2014/report/2014OzoneAssessment.pdf

[315] UNEP Environmental Effects Assessment Panel, 2022 Assessment Report of the Environmental Effects, Montreal Protocol on Substances that Deplete the Ozone Layer, UNEP Nairobi, Ozone Secretariat, March 2023, http://ozone.unep.org/science/eeap

Specifically, although TFA and its salts are persistent in the environment, "this persistence is not a major concern because TFA does not react with biomolecules," and TFA and its salts "do not bioaccumulate in food chains, … have low toxicity to animals and plants and there are very wide margins between current/projected exposures and toxicity values."[316] TFA released into the environment, which is a naturally occurring substance, "will eventually collect in terminal basins such as endorheic lakes or the oceans,"[317] where its potential for causing harm is minimal, and will not exceed thresholds for potential harm in rivers.[318] In the environment, TFA salts behave in the same way as salts of other minerals.[319]

Inter alia on these grounds, a UNEP Environmental Effects Assessment Panel concluded that "to regulate these [PFAS] substances as a class (as has been suggested) is not scientifically defensible and TFA should be treated as a unique chemical for the purposes of regulation."[320]

Despite the vast differences in relevant properties, the PFAS proposal sweeps all 10,000+ PFAS on the same pile, including those that have not yet been synthesized. How unscientific this practice is illustrated nicely by a recent answer from UNEP to the question "[w]ill chemicals that replace existing ozone-depleting substances bring new environmental problems?":

> "[F]or lakes and oceans, the effects of increased concentrations of naturally occurring mineral salts, such as sodium chloride, and other water-soluble minerals are greater and more biologically significant than those caused by TFA salts. Salts of TFA in soil are taken up by plant roots and concentrate in the leaves, where they appear to have no effects. If animals eat the leaves, TFA is rapidly excreted and does not accumulate in their bodies or in the food chain."[321]

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[316] UNEP Environmental Effects Assessment Panel, 2022 Assessment Report of the Environmental Effects, Montreal Protocol on Substances that Deplete the Ozone Layer, UNEP Nairobi, Ozone Secretariat, March 2023, http://ozone.unep.org/science/eeap, p. 292.

[317] UNEP Environmental Effects Assessment Panel, 2022 Assessment Report of the Environmental Effects, Montreal Protocol on Substances that Deplete the Ozone Layer, UNEP Nairobi, Ozone Secretariat, March 2023, http://ozone.unep.org/science/eeap, p. 293.

[318] The proponents provide no evidence that thresholds will be exceeded. Modeling suggests that steady-state concentrations of TFA in Rhine river basins will be reached within two months and will not exceed 10 µg/l. Ramboll Environment & Health, Trifluoroacetic Acid (TFA) Environmental Modelling, Memorandum, Ramboll Environment & Health, May 12, 2023.

[319] Keith R. Solomon, Guus J. M. Velders, Stephen R. Wilson, Sasha Madronich, Janice Longstreth, Pieter J. Aucamp & Janet F. Bornman (2016) Sources, fates, toxicity, and risks of trifluoroacetic acid and its salts: Relevance to substances regulated under the Montreal and Kyoto Protocols, Journal of Toxicology and Environmental Health, Part B, 19:7, 289-304, DOI: 10.1080/10937404.2016.1175981.

[320] UNEP Environmental Effects Assessment Panel, 2022 Assessment Report of the Environmental Effects, Montreal Protocol on Substances that Deplete the Ozone Layer, UNEP Nairobi, Ozone Secretariat, March 2023, http://ozone.unep.org/science/eeap, p. 292. "These releases will add to the existing load of TFA in the environment but predicted amounts are well below the threshold for concern with respect to human and environmental health."

[321] UNEP, Ozone Secretariat, Questions and Answers about the Effects of Ozone Depletion, UV Radiation, and Climate on Humans and the Environment Supplement of the 2022 Assessment Report of the UNEP

4) Presumed benefits of emission reduction

In short, in the view of the proponents of the PFAS restriction, estimated emissions are a solid proxy for risk. Emission reduction is assumed to translate into risk reduction, even though there is no solid evidence to support the proposition that all PFASs substances falling within the scope of the proposed restriction present a hazard, are released into environment at the rates posited by the proponents, and, upon release into the environment, reach concentration levels at which they could pose a potential risk.

The emission estimates, environmental concentrations, and exposure estimates produced by the proponents appear to be not only overestimations, but also to fail to support the key set of linked hypotheses underlying the PFAS proposal that "[c]ontinued emissions of PFASs … will result in an increasing environmental stock and, hence, increasing exposures," creating "a high likelihood that known thresholds of PFASs to cause adverse effects – as well as yet unknown thresholds - are exceeded."[322]

The best available science provides no support for these hypotheses. To hide this deficiency, the proponents resort to rhetoric rather than science or law where they state that "[s]ome scientists argue that the planetary boundaries for PFASs have already been exceeded."[323] Suffice it to recall that the EU REACH Regulation is not aimed at ensuring that some imaginary planetary boundary is met.[324]

v. Non-threshold substances

The acknowledgment by the proponents of the proposed restriction that there are both known and unknown thresholds for PFAS to cause adverse effects is important, if only because PBT/vPvB substances are regarded as non-threshold substances and not all PFAS substances are PBT/vPvB substances.

Environmental Effects Assessment Panel, June 2023, https://ozone.unep.org/system/files/documents/EEAP-assessment-report-2022-QA.pdf

[322] PFAS Proposal, p. 48.

[323] PFAS Proposal, p. 1.

[324] Cf. Montoya, José M., Ian Donohue, and Stuart L. Pimm, Why a Planetary Boundary, If It Is Not Planetary, and the Boundary Is Undefined? A Reply to Rockström et al., Trends in ecology & evolution 33.4 (2018): 234, https://doi.org/10.1016/j.tree.2018.01.008 Hanekamp, J.C., Verstegen, S.W., Vera-Navas, The historical roots of precautionary thinking: the cultural ecological critique and 'The Limits to Growth', Journal of Risk Research 2005, 8(4): 295 – 310.

1) Linear non-threshold (LNT)

For purposes of regulating chemical risk, the linear non-threshold (LNT) model is often misleading[325] or not helpful, as it has a limited scope of application.[326] In addition to the LNT model, the concepts of practical, statistical or mode of action thresholds have been pioneered.[327] The proponents of the PFAS restriction seem to be oblivious to these developments, however.

A basic problem of the LNT model is that substances do have thresholds, and, accordingly, the REACH Regulation recognizes thresholds such as derived no-effect level (DNEL) or predicted no-effect concentration (PNEC).[328] To overcome this issue, the PFAS proposal's insistence on persistence serves to persuade people that whatever the threshold may be, if releases continue, any threshold will eventually be exceeded.

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[325] The theory of "hormesis" posits that low dose chemical exposures may have beneficial effects. See, for instance, Calabrese, E.J., Baldwin, L.A., Hormesis: A Generalizable and Unifying Hypothesis. Critical Reviews in Toxicology 2001, 31(4&5): 353 – 424. Wiener, J.B., Hormesis and the Radical Moderation of Law. Human & Experimental Toxicology 2001, 20(3): 162 – 164. Calabrese, E.J., Baldwin, L.A., Toxicology Rethinks its Central Belief. Hormesis Demands a Reappraisal of the Way Risks are Assessed. Nature 2003, 421: 691 – 692. Calabrese, E.J., Hormesis: a revolution in toxicology, risk assessment and medicine. EMBO Reports 2004, 5: S37 – S40. Hanekamp, J.C., Bast, A., Hormesis in a precautionary regulatory culture: models, preferences and the advancement of science. Human & Experimental Toxicology 2007, 26: 855 – 873. Calabrese, E.J., Hormesis and medicine. British Journal of Clinical Pharmacology 2008, 66(5): 594 – 617. Calabrese, E.J. 2012. NEPA, EPA and risk assessment: Has EPA lost its way? Regulatory Toxicology and Pharmacology 64: 267 – 268.

[326] For a forceful critique of the LNT model, see Calabrese, E.J., The road to linearity: why linearity at low doses became the basis for carcinogen risk assessment. Archives of Toxicology, 2009, 83: 203 – 225. Calabrese, E.J., Cook, R.R., Hanekamp, J.C., Linear No Threshold – The New Homeopathy. Environmental Toxicology and Chemistry, 2012, 31: 2723. Edward J. Calabrese, LNT and cancer risk assessment: Its flawed foundations part 1: Radiation and leukemia: Where LNT began, Environmental Research, Volume 197, 2021, 111025, https://doi.org/10.1016/j.envres.2021.111025 Edward J. Calabrese, LNT and cancer risk assessment: Its flawed foundations part 2: How unsound LNT science became accepted, Environmental Research, Volume 197, 2021, 111041, https://doi.org/10.1016/j.envres.2021.111041 Edward J. Calabrese, LNTgate: How scientific misconduct by the U.S. NAS led to governments adopting LNT for cancer risk assessment, Environmental Research, Volume 148, 2016, pp. 535-546, https://doi.org/10.1016/j.envres.2016.03.040 Edward J. Calabrese, Flaws in the LNT single-hit model for cancer risk: An historical assessment, Environmental Research, Volume 158, 2017, pp. 773-788, https://doi.org/10.1016/j.envres.2017.07.030 Edward J. Calabrese, Paul B. Selby, Cover up and cancer risk assessment: Prominent US scientists suppressed evidence to promote adoption of LNT, Environmental Research, Volume 210, 2022, 112973, https://doi.org/10.1016/j.envres.2022.112973 For further discussion, see Jan Beyea, Response to 'On the origins of the linear no-threshold (LNT) dogma by means of untruths, artful dodges and blind faith', Environmental Research, Volume 148, 2016, pp. 527-534, https://doi.org/10.1016/j.envres.2016.01.039 Bill Sacks, Jeffry A. Siegel, Jan Beyea mischaracterizes the work by Siegel et al. (2016), Environmental Research, Volume 150, 2016, p. 663, ISSN 0013-9351, https://doi.org/10.1016/j.envres.2016.05.032

[327] In the context of genotoxic effects, see Hermann M. Bolt, Chapter 8 - Practical Thresholds in the Derivation of Occupational Exposure Limits (OELs) for Carcinogens, Editor(s): Takehiko Nohmi, Shoji Fukushima, Thresholds of Genotoxic Carcinogens, Academic Press, 2016, pp. 117-128. Joint Task Force ECHA Committee for Risk Assessment (RAC) and Scientific Committee on Occupational Exposure Limits (SCOEL) on Scientific aspects and methodologies related to the exposure of chemicals at the workplace, Task 2, Final Report, 6 December 2017, https://echa.europa.eu/documents/10162/13579/jtf_opinion_task_2_en.pdf/db8a9a3a-4aa7-601b-bb53-81a5eef93145

[328] These thresholds are to be established for a substance in accordance with Annex I of the REACH Regulation.

This reasoning is not scientific, however, since it does not show what the threshold is, nor how persistence results in it being exceeded – both are critically important issues that cannot be brushed aside by an unproven theoretical argument.

2) Arguments supporting non-threshold 'nature'

The central claim is that "risks of PFASs are of a non-threshold nature,"[329] despite the explicit, and contradictory, acknowledgement that known and unknown thresholds exist. [330] The use of the term "non-threshold nature" reveals confused thinking – whether a substance should be regarded as non-threshold is not inherent to its nature, but is dictated by regulatory science and standards.

While the proponents admit that "not all PFASs are PBT substances, the concerns raised for them compare with the concerns for PBT/vPvB substances." How this comparison justifies a conclusion that all PFASs should be treated as PBT/vPvB substances, however, remains in the dark. The proponents realize that their argument is weak and add that "[a]dditional concerns regarding mobility and long-range transport potential of PFASs justify a non-threshold approach."[331]

This argument also misses its target, because mobility and long-range transport apply only to a subgroup of PFAS substances, not to the entire group as defined. In addition, and more importantly for current purposes, even as to those substances that are mobile and show long-range transport potential, these properties are no substitutes for the legislative standards, and do not warrant a finding of non-threshold substance, not of unacceptable risk.

3) Precedent

The proponents claim further that their proposition that "PFASs should be treated as non-threshold substances for the purpose of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment and environmental monitoring data regarded as a proxy for an unacceptable risk," [332] is also supported by precedent.

"In accordance with previous restriction proposals on non-threshold substances," they argue that "every emission to the environment increases the likelihood of adverse effects" and "[t]herefore, current and future emissions have to be minimized."[333] But how could

[329] PFAS Proposal, p. 190.
[330] See, for instance, this statement: "It should be noted that for the most sensitive endpoints related to human health, such as effects on the immune system, and in highly exposed populations, effect thresholds of the most studied long-chain PFASs (PFOA and PFOS) are already exceeded today (EFSA, 2020)." PFAS Proposal, p. 48.
[331] PFAS Proposal, p. 190.
[332] PFAS Proposal, p. 190.
[333] "The proposed restriction enables a regulatory path to prevent the increase of general PFAS exposures." PFAS Proposal, p. 190.

previous restriction proposals support a deviation from existing legislative standards? The proponents go around in circles, but do not answer this question.

4) No support from OECD

In this regard, the overly broad PFAS definition gives rise to an additional objection to the generalization of persistence to all PFAS substances. Even if some PFAS substances meet the criteria for persistence, this property cannot be imputed to all PFAS as defined.

As the OECD confirmed, the broad PFAS definition is intended to understand the PFAS universe and does not imply that "all PFASs have the same properties, uses, exposure and risks."[334] This is not different for persistence and 'non-threshold nature'. As for all other properties, whether hazardous or non-hazardous, persuasive scientific evidence is required to impute persistence or 'non-threshold nature' to all substances belonging to a defined category.

By their own admission, the proponents are unable to furnish that evidence, and lament that "for most PFASs there are insufficient data to adequately assess their effects on human health and the environment."[335] Even where that is true, restrictions are no lawful, legitimate substitute for generating data on substances.

5) Implications of non-threshold treatment

Furthermore, the proponents are confused about the implications of the non-threshold treatment of a hazard. Even if all PFASs were PBT/vPvB substances and therefore non-threshold, that does not mean that they therefore should be regarded, by definition, as causing "unacceptable risk" for purposes of restrictions under the REACH Regulation. Exactly this, however, is what the proposal seems to suggest where it states that "due to the non-threshold nature of the hazards, the risks cannot be quantified" and, accordingly, "current releases of PFASs should be minimised" and "[a]ny release should be considered a proxy for risk."[336]

Even if the assumption underlying the thesis that hazard should be equated with risk, is accepted, more is required to label any such risk "unacceptable" with respect to the thousands of substances as to which no evidence of toxicity is presented.

[334] OECD, Reconciling Terminology of the Universe of Per-and Polyfluoroalkyl Substances: Recommendations and Practical Guidance. OECD Environment, Health and Safety Publications, Series on Risk Management No. 61. Organisation for Economic Co-operation and Development, 2021, https://one.oecd.org/document/ENV/CBC/MONO(2021)25/En/pdf , p. 25.
[335] PFAS Proposal, p. 13.
[336] PFAS Proposal, p. 50.

6) No reversal of the burden of proof on non-threshold treatment

In a further move, the proponents attempt to turn this counterargument around. Rather than that the regulator will have to prove that risk exist, they claim that "data is limited, or missing, to assess (i) the hazard of many of the individual PFAS substances; (ii) the associated thresholds below which exposure is not expected to lead to adverse health effects, if such limits exist, (iii) the combined effects of co-occurring PFASs, and (iv) the prediction of future human exposure levels."[337] How the absence of data justifies a deviation from the applicable legal standards, however, remains unclear. If there is no data, data should be generated, rather than substances banned.

As noted above, also in relation to the issue of non-threshold treatment, reversal of the burden of proof is not permitted under the REACH Regulation, nor under any principles of EU law, including the precautionary principle (see further below). A restriction pursuant to the REACH Regulation requires that "unacceptable risk" be demonstrated. The proponents' acknowledgement that there is no data to demonstrate any risk for many of the individual PFAS substances implies that the legal standard has not been met.[338]

7) Conclusions

In short, the non-threshold concept, assuming it applies to PFAS, provides no blanket exemption from the requirements for restriction under the REACH Regulation. True, the EU legislature has created separate criteria for PBT and vPvB substances, but even if all PFASs meet those criteria (which the proponents admit is not the case), neither PBT nor vPvB substances automatically, without more, require restriction.

The REACH Regulation's restrictions regime requires unacceptable risk in all cases. Rhetorical arguments in relation to the presumed 'non-threshold nature' of PFAS substances cannot result in a finding of unacceptable risk. To suggest that PFAS substances are eligible for restriction, the proponents distort the concepts of "non-threshold substance" and "unacceptable risk" by injecting extensive subjective value judgments into the assessment.[339] If such judgments are required, however, they should be made by politically

[337] PFAS Proposal, p. 140.
[338] Despite their plaint that there is no data, the proponents see no problem in setting thresholds for PFAS own, in another substance, as a constituent, in mixtures or in articles placed on the market. PFAS Proposal, p. 192.
[339] Cf. Colin L. Berry, Relativism, regulation and the dangers of indifferent science: The Sir Roy Cameron lecture of the Royal College of Pathologists, Toxicology, Volume 267, Issues 1–3, 2010, pp. 7-13, https://doi.org/10.1016/j.tox.2009.11.005, https://www.sciencedirect.com/science/article/pii/S0300483X09005812 ("the data obtained by use of the scientific method may be of a different kind from that which depends on opinions, honed by prejudices. Here I use prejudice to mean a bias that may be favourable or unfavourable to a particular viewpoint, rather than to a wilful disregard of fact or an unreasoning predilection to arrive at a particular answer—the Precautionary Principle is a good example of only considering results that fit a preconceived viewpoint.")

accountable decision-makers, not by risk assessors or regulators that read their own desires into the law.[340]

Science should not be misused in attempting to quantify and regulate unmeasurable hazards and risks.[341] If hazards cannot be measured and, thus, science is unable to evaluate them, science should not be invoked to justify risk assessments in health, safety and environmental regulations."[342] Where independent scientific evidence is not possible, "policies and regulations should be informed by publicly debated trade-offs between socially desirable uses and social perceptions of affordable precaution."[343]

vi. Precautionary Principle and Burden of Proof

The elusive precautionary principle is probably the most controversial principle of the EU's environmental policy principle and for good reasons.[344] If applied to all risks on all sides of a problem, including the proposed intervention, the principle ignores risk/risk trade-offs[345] and is pointless or 'paralyzing.'[346] Capitalizing on scientific uncertainty, the principle is invoked to ease the burden of proof imposed on government or even to reverse it.[347]

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[340] Cf. ERIF, Novel Regulatory Philosophies – Future Directions and Implications for Risk Management, Highlights Note 21, March 2023.

[341] An Appeal for the Integrity of Science and Public Policy, Toxicology, September 4, 2016, doi:10.1016/j.tox.2016.08.015

[342] Cf. Sir Colin Berry, Reproducibility in experimentation – the implications for regulatory toxicology, Toxicology Research, Volume 3, Issue 6, November 2014, Pages 411–417, https://doi.org/10.1039/c4tx00069b

[343] Michael Aschner, Herman N. Autrup, Sir Colin L. Berry, Alan R. Boobis, Samuel M. Cohen, Edmond E. Creppy, Wolfgang Dekant, John Doull, Corrado L. Galli, Jay I. Goodman, Gio B. Gori, Helmut A. Greim, Philippe Joudrier, Norbert E. Kaminski, Curtis D. Klaassen, James E. Klaunig, Marcello Lotti, Hans W.J. Marquardt, Olavi Pelkonen, I. Glenn Sipes, Kendall B. Wallace, Hiroshi Yamazaki, Upholding science in health, safety and environmental risk assessments and regulations, Toxicology, Vol. 371, 2016, pp. 12-16, https://doi.org/10.1016/j.tox.2016.09.005, https://www.sciencedirect.com/science/article/pii/S0300483X16302037

[344] For analyses of the origins and consequences of the precautionary approach, see Pieterman, R. 2001. Culture in the Risk Society. An Essay on the Rise of a Precautionary Culture. Zeitschrift für Rechtssoziologie , 2001, 22(Heft 2): S. 145 – 168. Hanekamp, J.C., Verstegen, S.W., Vera-Navas, The historical roots of precautionary thinking: the cultural ecological critique and 'The Limits to Growth', Journal of Risk Research 2005, 8(4): 295 – 310. Hanekamp, J.C., Verstegen, S.W., The Problematic Precautionary Paradigm: the Paternalism of the Precautionary Coalition. In: Panton, J., Hartwich, O.M. (eds.) Science vs Superstition. The Case for a New Scientific Enlightenment. University of Buckingham Press, Buckingham, 2006, pp. 22 – 34. Hanekamp, J.C., Utopia and gospel: Unearthing the good news in precautionary culture. Doctoral Thesis, Tilburg School of Humanities and Digital Sciences, 2015.

[345] Wiener, J.B., Precaution in a Multi-Risk World. Duke Law School Public Law and Legal Theory Working Paper Series Working Paper No. 23, 2001. Cf. John D. Graham, Jonathan Baert Wiener, Risk vs. Risk: Tradeoffs in Protecting Health and the Environment, Harvard University Press, 1995.

[346] "The principle is literally paralyzing - forbidding inaction, stringent regulation, and everything in between. The reason is that in the relevant cases, every step, including inaction, creates a risk to health, the environment, or both." Sunstein, C. R. (2002). Beyond the precautionary principle. U. Pa. L. Rev., 151, 1003. Sunstein, C.R., Beyond the Precautionary Principle. Public Law and Legal Theory Working Paper No. 38, 2003, available at http://ssrn.com/abstract_id=307098. Sunstein, C.R. 2005. Laws of Fear: Beyond the Precautionary Principle. Cambridge University Press, Cambridge.

[347] L. Bergkamp, Understanding the Precautionary Principle, Parts I and II, Environmental Liability, 18–30 and 67–82 (2002). L. Bergkamp & L. Kogan, Trade, the Precautionary Principle, and Post-Modern Regulatory

1) Precaution creeping into risk assessment

While originally positioned as a principle that applies only to risk management, it is now being invoked also in the area of scientific and risk assessments. As the Commission stated, "[t]he precautionary principle should be considered within a structured approach to the analysis of risk which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk."[348]

Despite these assurances, the principle crept into risks assessment in some instances.[349] In the case of the PFAS proposal, however, the entire proposal breathes precautionary thinking and could not been made with broad reliance on the permissions it is presumed to grant.

2) Implicit reliance on precautionary principle

Although the proponents of the PFAS proposal apply extensive precautionary reasoning, they do not invoke the precautionary principle.[350] In their estimation, it probably seemed wise not to rely explicitly on this principle to support the proposal, since its application is rife with pitfalls and requires value judgments that they are not authorized to make.

Despite their reluctance to rely explicitly on the principle, their entire argument applies a precautionary approach. This is evident from their emphasis on uncertainties, the extrapolation of data on potential adverse effects, and the application of worst-case scenario thinking.[351] Inasmuch as the proposal is based on the putative requirement that all synthetic chemicals be biodegradable, it also embodies the "naturalistic fallacy"[352] —

Process: Regulatory Convergence in the Transatlantic Trade and Investment Partnership, (4) Eur. J. Risk Reg. 493–507 (2013).

[348] European Commission, Communication on the Precautionary Principle, COM(2000) 1 final , Brussels, 2.2.2000, https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:en:PDF

[349] L. Bergkamp, The Quite Revolution in EU Administrative Procedure: Judicial Vetting of Precautionary Risk Assessment - Case T-333/10, ATC and Others v Commission, 16/09/2013 ('Animal Trading'), European Journal of Risk Regulation 2014, pp. 102-110.

[350] They refer to the precautionary principle in one instance: "Transport Canada allowed airports to use PFAS-free firefighting foam, which shows a more precautionary approach as it targets the whole class of PFASs." PFAS Proposal, p. 67.

[351] "The similarity of the effects of most PFAS groups, often targeting the same organs, raises concerns about cumulative effects of PFASs. The lack of toxicity data for most PFASs precludes precise modelling of combined effects of all PFASs but concentration addition has been suggested as a precautious first tier, irrespective of the modes/mechanisms of action of the mixture components. This may give a realistic worst case estimation of combined toxicities for risk assessment procedures even if similarity of components is unknown." Annex XV Restriction Report, PFASs, 22 March 2023, p. 32.

[352] Sinclair N. (editor), The Naturalistic Fallacy, Cambridge University Press, 2019. Cf. Hanekamp, J.C., Utopia and gospel: Unearthing the good news in precautionary culture. Doctoral Thesis, Tilburg School of Humanities and Digital Sciences, 2015.

specifically, the idea that 'biodegradable must be good' because many biomolecules degrade.

3) Absence of data and reversal of burden of proof

In the PFAS proposal, the absence of complete data sets on all PFAS substances is positioned as the key problem, which supplies the rationale for reversing the burden of proof.[353] The absence of proof of safety is treated as proof of the absence of safety.[354]

For instance, the proponents posit that because "for the vast majority of these substances, no study data are available to serve as a basis for classification … in the absence of evidence to the contrary, it can therefore be assumed that some of the less well-studied PFAAs and PFAA precursors also exhibit one or more of the properties of concern."[355] The argument simply is that chemical regulation "must leave behind the "innocent-until-proven-guilty" approach" and embrace the precautionary approach.[356]

4) Relaxing risk assessment and cost-benefit analysis

The implicit application of precautionary approach in the PFAS proposal serves to invoke uncertainty as a justification or excuse to relax the two basic tenets of risk regulation: risk assessment and cost-benefit analysis. Precaution should excuse the absence of data on most PFAS substances because there is some data on some substances that shows hazard or risk. According to the proponents, precaution should justify an assumption that all PFAS substances falling within the scope of the proposed restriction pose unacceptable risk. Precaution requires that the worst possible consequences be taken as the point of reference. Precaution excuses also the absence of any hard cost/benefit analysis.

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[353] The following statement from a report on PFAS by the European Environment Agency, to which the PFAS proposal refers, provides an example: "It is currently not possible to perform in-depth environmental and health risk assessments of all chemical substances in use in Europe because of the great variety of chemicals and their diverse uses. New and legacy chemicals continue to be released into Europe's environment, adding to the total chemical burden on Europe's citizens and ecosystems. Early identification of emerging risks is one of the activities of the European Environment Agency (EEA)." European Environment Agency, Emerging chemical risks in Europe — 'PFAS', Copenhagen, December 2019, https://www.eea.europa.eu/publications/emerging-chemical-risks-in-europe

[354] "Even though there is still a large number of PFASs that have no (self-)classification for the properties of concern, the absence of classification does not mean that these PFASs do not have these properties." PFAS Proposal, p. 30.

[355] PFAS Proposal, p. 30.

[356] Samuel Boden, Presumptive Innocence v. the Precautionary Principle: The Story of PFAS Regulation in the United States, UC Davis Law Review, Vol. 44, 2021, pp. 37-62. ("It is clear that any successful PFAS regulation must tackle the chemicals as an entire class and provide regulators with the tools to gather data on potential harms from the chemicals, shifting the burden onto manufacturers to prove that their products are not harmful. But disclosure is not enough—it must be paired with increased enforcement power.")

5) Breach of conditions for application of precautionary principle

The PFAS Proposal implicitly applies the precautionary principle in a way that violates the conditions under which this principle may be applied.[357] There is no scientific uncertainty in relation to many substances covered by the proposal. The precautionary principle was not intended to be applied to hazard and risk assessment, as opposed to risk management.[358] With the PFAS Proposal this important distinction is ignored, and chemical risk regulation would be further drawn into precautionary hazard assessment, which results in vaguely defined "precaution" penetrating all phases of chemical regulatory processes, including scientific processes, thus greatly distorting final risk management decisions.[359]

Further, for most of the substances covered by the PFAS Proposal, the proponents have not completed the four steps of scientific risk assessment recommended by the Commission,[360] they have not confirmed the effectiveness and proportionality of the proposed measures, and they do not require that the data gaps be filled so that any scientific uncertainty be resolved and the measures can be reviewed in light of new scientific data.[361]

In other words, in the name of protecting the environment and health, the precaution principle as implicitly applied by the proponents would wipe out all protections offered by law against unauthorized and unjustified government risk management interventions. The proponents' default assumption is that all PFAS substances pose unacceptable risk, and only if companies provide affirmative evidence demonstrating absence of risk in particular cases, can this assumption be overridden.[362] Although the REACH Regulation refers to the precautionary principle,[363] no such expansive application of the principle to set aside the legal standards could possibly be read into the law. The PFAS Proposal therefore cannot be supported by the precautionary principle.

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[357] European Commission, Communication on the Precautionary Principle, Brussels, 2.2.2000, COM(2000) 1 final2000, available at https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:en:PDF
[358] European Commission, Communication on the Precautionary Principle, Brussels, 2.2.2000, COM(2000) 1 final2000, available at https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:en:PDF
[359] Cf. Peterson, M. (2006). The precautionary principle is incoherent. Risk Analysis, 26(3), 595–601. Peterson, M. (2007). The precautionary principle should not be used as a basis for decision-making: Talking Point on the precautionary principle. EMBO Reports, 8(4), 305–308. Stefánsson, H. O. (2019). On the limits of the precautionary principle. Risk Analysis, 39(6), 1204–1222.
[360] These four steps are hazard identification, hazard characterization, exposure assessment, and risk characterization.
[361] European Commission, Communication on the Precautionary Principle, Brussels, 2.2.2000, COM(2000) 1 final2000, available at https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:en:PDF
[362] The European Commission and ECHA have problematized the absence of complete information on all chemical substances beyond the "no data, no market" principle enshrined in the REACH Regulation. Cf. Lofstedt, Ragnar, The Precautionary Principle in the EU: Why a Formal Review Is Long Overdue, Risk Management, vol. 16, no. 3, 2014, pp. 137–63.
[363] Article 1(3), REACH Regulation: "This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle."

6) *Possibilistic risk assessment*

To be sure, uncertainty is always an issue in risk regulation. There are ways to reduce and manage uncertainty, and uncertainty is not an argument to regulate.[364] The inclination to treat the mere possibility of harm as a justification for regulatory intervention has adverse consequences, however.

The shift from probabilistic to possibilistic risk management has been explained by skepticism about innovation, technological progress, and the capacity of knowledge to help manage risks, which has "encouraged the dramatisation of uncertainty."[365] An overemphasis on uncertainty also creates perverse incentives for science to find uncertainty, which has a series of undesirable consequences.[366] If there is too much focus on uncertain worst-case scenarios without an ability to assign probabilities to such scenarios, cost-benefit analysis becomes increasingly useless. As a result, society will have no basis for judging whether proposed regulations are worthwhile.

7) *Dismal theorem*

In line with this precautionary thinking, the proponents of the PFAS restriction attempt to paint a picture of large structural uncertainty and widespread, large-scale possible harm to the environment and human health. The idea is that given the enormous size of the harm, even if the probability is very low, it is still worthwhile to take rigorous measures, i.e. impose bans.

This represents an application of the "dismal theorem," which suggests that society should be willing to devote to make very substantial sacrifices to protect against widespread, serious future harms.[367] If this kind of thinking is generalized, which would be entirely logical to do, it becomes clear that the implications would be unacceptable.[368] For instance, should society invest all of its resources in defense, if there is a possible threat of a devastating nuclear war? This point shows again that the precautionary approach is (and can be) applied

[364] See, for instance, Jeroen van der Sluijs, Uncertainty as a monster in the science-policy interface: four coping strategies, Water Sci Technoly 2005; 52(6), pp. 87-92.
[365] F. Furedi, Precautionary Culture and the Rise of Possibilistic Risk Assessment, Erasmus Law Review 2009, pp. 197–220.
[366] Cf. Bergkamp, Lucas, The 'iron triangle' and the rise of the counter-norms of science – Parts I and II, Environmental Law & Management, 2017, Volume 28, Issue 6, pp. 247-258 & Volume 29, Issue 1, pp. 16-26. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3534816
[367] The Dismal Theorem was first developed in the context of climate change. Cf. Weitzman, M.L., On modeling and interpreting the economics of catastrophic climate change, Rev. Econ. Stat., 91 (1), 2009, pp. 1-19. Cf. Horowitz, John, Lange, Andreas, Cost–benefit analysis under uncertainty — A note on Weitzman's dismal theorem, Energy Economics, 2014, Vol.42, pp. 201-203. Cf. Durodie, B. (2000). Calculating the cost of caution. Chemistry & Industry, 1(5), 170.
[368] Nordhaus, W.D., The economics of tail events with an application to climate change, Rev. Environ. Econ. Policy, 5 (2), 2011, pp. 240-257. Cf. Frisch M., Modeling Climate Policies: The Social Cost of Carbon and Uncertainties in Climate Predictions. In: A. Lloyd E., Winsberg E. (eds) Climate Modelling. Palgrave Macmillan, Cham, 2018.

only in an arbitrary fashion to some risks, while completely ignoring other risks, including risks to the environment and human health.[369]

8) Misapplying worst case rule

Implied in the PFAS proposal is the idea that the 'worst cases' within the group of all PFAS substances should be deemed decisive for the properties of the entire group. On this basis, the hazardous properties of a few PFAS substances are effectively imputed to all other PFAS substances. In the context of the REACH Regulation, a version of the 'worst case' rule is indeed applied, but the conditions under which it may be applied are not met in the case of the proposed PFAS restriction.

Under the REACH Regulation, the 'worst case' rule is applied in the context of PBT/vPvB assessment of, *inter alia*, multiconstituent substances (MCSs). To avoid testing of all individual constituents of a MCS, testing may be limited to only some constituents if (i) the MCS is "*a priori* known to contain specific constituents at relevant concentrations," (ii) these constituents "are suspected based on available information to represent the worst case of the (v)P, (v)B and T properties of all constituents of the substance," and (iii) these specific constituents "can be isolated or separately manufactured or otherwise acquired for the purpose of testing." [370] This exception requires "justification that any representative constituent chosen for testing is a reasonable worst case."[371]

None of the conditions for the application of the 'worst case' rule, however, are met in the case of the PFAS restriction. First, in terms of consequences, subjecting substances to restrictions is fundamentally different from avoiding unnecessary testing – a restriction implies a ban or concentration limit for the substance concerned, but testing does not limit the use of a substance at all. Second, while all constituents of a MCS are always present simultaneously, this is not the case for PFAS substances, which are individual, separately existing products. Third, there is no "a priori" reason to assume that the PFAS substances that have been found to be hazardous are present in other PFAS substances; to the contrary, analytical data often demonstrate that they are not present. Thus, insofar as the proponents might be inclined to invoke the 'worst case' rule, they would not only make a category mistake, but also violate the conditions for application of the rule.

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[369] Cf. Bill Durodié, The True Cost of Precautionary Chemicals Regulation, Risk Analysis, Vol. 3, Issue2, April 2003, pp. 389-398. Majone G., What price safety? The precautionary principle and its policy implications, J. Common Market Stud, 40(1), 2002, pp. 89-109.

[370] ECHA, Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB assessment, Version 3.0, June 2017, p. 109, https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f

[371] ECHA, Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB assessment, Version 3.0, June 2017, p. 110, https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f

9) Conclusions

The precautionary approach that pervades the PFAS proposal blurs our view on the issues at stake in the proposed restriction of PFAS and distorts the regulatory decision-making process. The proponents invoke possibilistic risk assessments, hide the risk/risk trade-offs, and thus rig the costs and benefits of risk management options. Implicitly, their proposal espouses the idea that PFAS producers and users should be required to establish that their products and uses will not cause harm, which is logically impossible for substances that are deemed to be persistent if persistence equals risk of harm.[372] As Wildavsky explains, the precautionary principle is a marvelous piece of rhetoric:

> "It places the speaker on the side of the citizen – I am acting for your health – and portrays opponents of the contemplated ban or regulation as indifferent or hostile to the public's health. The rhetoric works in part because it assumes what actually should be proven, namely, that the health effects of the actions in view will be superior to the alternative. And this comparison is made favorable in the only possible way – by assuming also that there are no health detriments from the proposed regulation. The rhetoric seems to present a choice between health and money or even suggests health with no loss whatsoever, for a tangential presumption is that "industry will find a better and a cheaper as well as safe way." Something (health) is gained with nothing lost (no adverse health effects from the bans or regulations)."[373]

The precautionary PFAS restriction proposal embodies the view that even potential, hypothesized environmental and public health risks as a result of low-level exposure to synthetic chemicals are to be averted at all costs.[374] Cost-benefit and impact analysis is subordinate to this imperative. Even if there is some scientific uncertainty, however, the precautionary approach is an inadequate response to this problem.

c. Policy Issues

i. Actual Risk versus Perceived Risk

A possible justification for the PFAS proposal could be that it addresses the perceived, not the actual, risks of PFAS substances. Indeed, following incidents involving specific groups of PFAS substances, public media have paid much attention to PFAS. A 2016 New York Times article on PFOA pollution in the United States[375] was the basis for a popular movie.[376] A 2022 study found that "on social media, PFAS are perceived as an immediate public health concern."[377] Given that PFAS contamination is invisible to the human eye, and

[372] Cf. L Bergkamp, European Community Law for the New Economy, Antwerp, Intersentia, 2003. Cf. Sapolsky, H. (1990) The Politics of Risk, Daedalus 119-4, 83-96.
[373] A Wildavsky, But is it true? A citizen's Guide to Environmental Health and Safety Issues, Cambridge: Harvard University Press, 1997.
[374] R Pieterman and JC Hanekamp, The Cautious Society? An Essay on the Rise of the Precautionary Culture, Zoetermeer, 2002.
[375] Nathaniel Rich, The Lawyer Who Became DuPont's Worst Nightmare, New York Times, Jan. 6, 2016, https://www.nytimes.com/2016/01/10/magazine/the-lawyer-who-became-duponts-worst-nightmare.html
[376] Dark Waters, 2019, https://www.focusfeatures.com/dark-waters
[377] Tian H, Gaines C, Launi L, Pomales A, Vazquez G, Goharian A, Goodnight B, Haney E, Reh CM, Rogers RD,

bioaccumulation, environmental disaster and cancer sound scary,[378] it is understandable that the general public, which on average has scant knowledge of toxicology and received little scientific training, may become concerned about the possible consequences of releases of all PFAS substances. Thus, it is conceivable that there is a certain level of public anxiety.

1) Unlawful regulation of perceived risk

From an EU law perspective, in some cases, it may be appropriate to take action to address perceived risks, even in the absence of actual, physical risk. Indeed, the European Court has left an opening for restrictions or bans to allay perceived risks where physical risk has not been demonstrated. Such restrictions or bans may be lawful if they are suitable and necessary to dispel consumer anxieties, which may be unfounded, if the regulator may take the view that this objective "could not be achieved by means of less onerous measures such as the dissemination of information."[379] In other words, the measure must be a sufficient and necessary condition for restoring public confidence.

In the case of PFAS, however, this condition is not met. The proponents of the PFAS proposal do not argue that the proposed bans are sufficient and necessary to dispel public concerns about PFAS substances in general. If they were to attempt to develop this argument, they would likely have a hard time sustaining it for all PFAS substances. Moreover, the REACH Regulation does not entertain the idea that perceived chemical risk authorizes restrictions. To the contrary, the REACH Regulation makes crystal clear that the term "unacceptable risk" refers to actual, physical chemical risk. Thus, the allaying of public concerns about possible chemical risk does not provide a rationale for REACH restrictions.

2) Perceived chemical risk

The entire concept of regulating chemical substances on the basis of perceived, not actual risk is doubtful, however. The thinking behind this idea is that science is not essential to the identification of risk, that the distinction between objective risk and subjective risk is relative, and that real risk and perceived risk are "one and the same," as both are "social constructions."[380]

Understanding Public Perceptions of Per- and Polyfluoroalkyl Substances: Infodemiology Study of Social Media J Med Internet Res 2022;24(3):e25614, doi: 10.2196/25614

[378] The Union of Concerned Scientists warns that "PFAS are associated with many serious illnesses, including cancers and reproductive disorders." Union of Concerned Scientists, Time for Action to End PFAS Threat, Jan. 14, 2019, https://www.ucsusa.org/resources/pfas-threat

[379] Case C-331/88, The Queen v Ministry of Agriculture, Fisheries and Food, ex parte FEDESA and Others, Judgment of the Court (Fifth Chamber) of 13 November 1990, https://curia.europa.eu/juris/liste.jsf?language=en&num=C-331/88 ("the importance of the objectives pursued is such as to justify even substantial negative financial consequences for certain traders").

[380] Beck, Ulrich. 1992. Risk Society: Towards a New Modernity. Translated by Mark Ritter, Risikogesellschaft: Auf dem weg eine andere Modern. Frankfurt: Suhrkamp, 1986. London: Sage, p. 270.

In this postmodernist view, it does not matter whether "we live in a world that is "objectively" more secure than any that has gone before."[381] Needless to say, these propositions are diametrically opposed to rational science-based risk regulation, and would result in dubious rules for phantom risks. Indeed, the relativist, subjective view of risk has been powerfully rebutted[382] and rejected by legislatures around the world, including the EU.

3) Strategic risk

As the PFAS proposal demonstrates, allowing regulation of chemicals not based on objectively established risk, but on a subjective notion of perceived risk presents strategic risk. Once this door is opened, a basis for regulation can be created by stirring up public anxiety. Strategic operators could use any such opening to launch campaigns to attack activities or products they dislike in order to create sufficient public anxiety for regulation to be justified.[383]

There is no reason to have any confidence in the risk management capabilities of such a program. Perceived risk does not require a risk management measure that interferes with the activity that is believed to generate the risk. Perceived risk that does not exist in reality (i.e., outside the individual's mind) can be addressed by information campaigns and education.

As perception-based risk regulation is a prime generator of precautionary science and unfounded regulatory activism, combatting it also helps to alleviate these adverse effects. The remedy for erroneous public risk perceptions is not regulation of the perceived risks, but the dissemination of accurate information.[384]

ii. Weighing the Costs and Benefits of the PFAS Proposal

With its precautionary overtones, the impact assessment that accompanies the proposed PFAS restriction creates the impression of a subterfuge. As expected, it does not provide a sound cost-benefit analysis of the proposed restriction; it is not even an attempt to produce any such analysis. While it covers a wide range of possible impacts, it is structured and written to justify a predetermined result.

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[381] Beck, Ulrich. 2009. World at Risk. (Translated by Ciaran Cronin, Weltrisikogesellschaft, Frankfurt: Suhrkamp, 2007). Cambridge: Polity Press, p. 11.
[382] See, for instance, Wildavsky, A., But is it True? A Citizen's Guide to Environmental Health and Safety Issues. Harvard University Press, Cambridge, 1997. Cf. Ames, B.N., Gold, L.S., Chemical carcinogenesis: Too many rodent carcinogens, Proc Natl Acad Sci U S A. 1990 Oct; 87(19): 7772–7776.
[383] Cf. Hanekamp, J.C., Pieterman, R., Risk Communication in Precautionary Culture – The Precautionary Coalition. Human & Experimental Toxicology, 2009, 28: 15 – 20.
[384] L. Bergkamp, The Concept of Risk Society as a Model for Risk Regulation – Its Hidden and Not so Hidden Ambitions, Side Effects, and Risks, Journal of Risk Research 1–17 (22 Mar. 2016), http://dx.doi.org/10.1080/13669877.2016.1153500

1) Cost of precautionary substance bans

Even if all legal requirements were met, it is far from clear that the proposed PFAS restriction should be endorsed. Before any decision is made on the broad PFAS ban, it would be necessary to face, not dodge, the hard issues. Most of these issues center around the basic question what price society should be willing to pay for precautionary regulation intended to prevent possible unknown adverse effects of a large group of useful chemical substances with many applications throughout the economy. Answering this question requires not only a rigorous comparison of the relative costs and benefits of the proposed PFAS ban versus no action or more targeted action, but also of trading off one set of risks against another set of risks, which may be more serious.

The proponents of the PFAS ban dodge these issues by applying logical fallacies and rhetoric to sustain their overly broad grouping approach. In essence, they argue that the group must be extremely broad to avoid "regrettable substitution," but this argument is self-serving. The proponents have failed to demonstrate that substitution of hazardous substances with non-hazardous substances would be "regrettable." Rather, they want the reader to believe that all non-hazardous PFAS substances are also "hazardous," because they may be persistent.

The approach adopted by the proponents is unable to distinguish between regrettable substitution and desirable substitution and reflects an anti-PFAS bias. Regrettably, the proposed restriction creates a serious risk of regrettable stigmatization to avoid a hypothetical risk of regrettable substitution. Thus, the substitution caused by the PFAS ban itself would likely turn out to be quite regrettable.[385]

2) Cost of the PFAS ban

The PFAS proposal focuses on the potential and hypothetical risks of PFAS substances, which are no grounds for regulating under EU law,[386] but it neglects to focus, to any significant extent, on the actual and real risks of the ban on PFAS substances. Obviously, a PFAS ban will cause risks associated with the unavailability of these substances for a large range of applications.

PFAS substances are preferred over other substances that might serve the same or similar functions. Alternatives are not always available, and, where they are available, they often do

[385] Royal Society of Chemistry, Environment, Health and Safety Committee, Exploring the Practical Aspects of Chemical Substitution, 2007, https://substitution.ineris.fr/sites/substitution-portail/files/documents/rsc_2007.pdf Cf. Jacobs MM, Malloy TF, Tickner JA, Edwards S. 2016. Alternatives assessment frameworks: research needs for the informed substitution of hazardous chemicals. Environ Health Perspect 124:265–280, http://dx.doi.org/10.1289/ehp.14095

[386] Court of First Instance, Pfizer Animal Health SA, Case T-13/99, 11 Sept. 2002 ("[A] preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified" and "a 'zero risk' does not exist, since it is not possible to prove scientifically that there is no current or future risk associated with" the regulated activities/ products").

not perform as well as the PFAS substances they replace and may be more expensive. This kind of substitution may also mean that a hypothetical or remote risk of some adverse effect of PFAS in the future is replaced by a real, immediate risk of adverse effects associated with lower product performance now – for example, reduced performance sealants create occupational and personal safety risks as well as environmental risks resulting from leakage and spills of hazardous substances.

The social losses resulting from these bans are downplayed by the proponents of the PFAS ban. In short, no serious attempt has been made to assess "the socio-economic impact of the restriction, including the availability of alternatives," as the REACH Regulation requires. A limited assessment of alternatives is not a substitute for a socioeconomic impact or cost-benefit analysis.

3) Effects on economic freedom, consumer choice and innovation

Likewise, the effects of the PFAS ban on economic freedom and consumer choice receive little attention. There will be spill-over effects throughout the economy. Of course, investment in the substantial PFAS-related industry will be deterred, but the deterrence that results from non-science-based, arbitrary regulation will extend throughout all sectors.

While the proponents argue that the ban would stimulate innovation and incentivize the development of safe chemicals, the ban's actual effects on innovation will likely be far more sinister. In general, innovation cannot be effectively pursued through bans and restrictions, but where restrictions target innovative substances that have been developed in response to prior restrictions on other substances,[387] their deterring effects on innovation will be even stronger.

In response to prior regulation of hazardous PFAS substances, the EU industry invested in innovation and developing sustainable and safe alternatives to the hazardous substances. These alternatives would be banned without a scientifically valid reason. By throwing the industry under the bus, the EU would violate the legitimate expectations of companies that made these investments.

Moreover, much of the publicly funded science is concerned with identifying possible adverse effects of chemical substances, not helping the chemical industry with developing superior chemical products. Thus, from this angle, innovation is also deterred.

4) Effects on trade, competitiveness, and the global environment

Further, the proposed ban would have broad effects on international trade and competitiveness. The European PFAS industry and related sectors would disappear. Insofar

[387] For instance, short-chain alternatives have replaced long-chain PFASs. Cf. Jessica S. Bowman, Fluorotechnology Is Critical to Modern Life: The FluoroCouncil Counterpoint to the Madrid Statement, Environmental Health Perspectives 2015, 123:5 CID: https://doi.org/10.1289/ehp.1509910

as an industry will develop to replace it, this industry would face higher cost and would probably not be able to compete in international markets outside the EU.[388]

At the same time, as PFAS in the environment is a global issue, there is no guarantee that the background level of PFAS in Europe's environment will drop significantly as long as there are sources outside the European Union that will release PFAS. Rather than outlaw Europe's PFAS-related industry, if restrictions are deemed necessary, an international treaty would be a much more effective way to proceed. If the EU were to adopt a broad PFAS ban unilaterally, this would reduce, not augment, the incentives for other countries to agree to similar restrictions.

5) A better regulatory approach

Instead of the shotgun approach utilized by the proponents of the PFAS ban, a targeted approach should be considered.[389] Under this approach, only known hazardous PFAS substances posing risk would be regulated specifically to manage the risk and bring it down to an acceptable level. If, at any point in time, another PFAS substance is found to be hazardous too, this substance would also be regulated. Non-hazardous PFAS substances that pose no risk would not be regulated merely because they show some structural commonality with hazardous PFAS substances.

The proponents' argument that this way of regulating would be "inefficient," assumes that there will continue to be many cases of PFAS substances that in due course will turn out to be hazardous. There is no evidence for the veracity of this proposition, however. Even if "the SVHC identification of all PFASs fitting the chemical definition would be very difficult,"[390] that is no argument to support the easy way out and ban all PFAS substances. A default assumption that substances are hazardous is unworkable and highly inefficient. In any event, no such value judgment can be made by regulators under the restriction regime of the REACH Regulation.

Thus, the proponents' argument that only a complete ban, subject to derogations, will be effective to address the risks of PFAS substances is unpersuasive at various levels. The proposed remedy is worse than the disease. Instead of a ban, a principle such as "as low as reasonably achievable" would be a much better guide to address the possible risks associated with hazardous PFAS. At the same time, any data gap in relation to PFAS substances can be addressed. Apparently, however, the authorities that are pushing this ill-considered ban do not want science-based and reasonable regulation. Yet, this is exactly what the legislature prescribed.

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[388] Whether the United States will adopt PFAS bans as broad and as stringent as the EU's bans is doubtful. Cf. Ansell, Chris, and Jörg Balsiger, Circuits of regulation: transatlantic perspectives on persistent organic pollutants and endocrine disrupting chemicals, Transatlantic Regulatory Cooperation, Edward Elgar Publishing, 2011.
[389] This would be a modified version of the current approach on a sounder scientific basis and at a faster pace, as necessary and appropriate to address risks presented by specific PFAS. Cf. PFAS Proposal, pp. 64-65.
[390] PFAS Proposal, p. 69.

d. Summing up

The proposed PFAS restriction, which represents a move away from traditional concepts of chemical risk regulation, flies in the face of science and the scientific method, violates the REACH Regulation, general principles of EU law, and human rights, deters innovation and investment in the EU, and may well increase safety risks. Some of the most egregious problems associated with the PFAS Proposal relate to the definition of PFAS, the use of the grouping approach, and the equating of persistence with risk and harm.

The definition of PFAS included in the PFAS proposal is based on the OECD definition, which is descriptive and not intended for regulatory purposes, let alone restrictions. It includes a wide range of widely different substances: (i) HFC/HFO fluorocarbons (C2-C4), (ii) the entire OECD PFAS C4-C14 library of approx. 4,700 chemicals, and (iii) PCTFE fluoropolymers with a molecular weight of approx. 249,000. The "remedy" proposed by the proponents, i.e. granting derogations, does not cure the fundamental deficiency of the overly broad PFAS definition and inappropriately (and unlawfully) reverses the burden of proof.

1) Assuming, not proving risk

The reasoning of the proponents to justify the use of this broad definition is circular. According to the draftsmen, it would be better to regulate PFAS as a group to avoid "regrettable substitution," but it is merely assumed, but not proven, that substitution will be regrettable, rather than desirable. The argument developed by the proponents effectively results in the circular, evidence-free argument that 'PFAS are a group because they pose the same hazard, and PFAS share the same hazard because they are a group.'

Persistence is not a hazard; it is only considered in connection with bioaccumulation and toxicity. A substance that is persistent, but not bioaccumulative or toxic, cannot be hazardous. A non-hazardous substance, by definition, cannot present risk, which is defined with reference to exposure to hazard. A PBT or vPvB assessment can only be done on a specific substance; it cannot be done on a group of substances as broadly defined and as varying as PFAS. Further, no argument is made that any PBT or vPvB hazard of any PFAS meets the criteria for grouping or read-across so that it can be imputed to all other PFAS falling within the scope of the PFAS Proposal. The proponents have even failed to provide "scientific evidence of probable serious effects to human health or the environment" equivalent to the hazards/risks covered by the REACH Regulation. Accordingly, the proponents have failed to demonstrate that the vast majority of PFAS covered by the PFAS proposal are hazardous, let alone that they pose "unacceptable risk."

Like persistence, emission is an inappropriate and unreliable proxy for risk or harm. Emission of a persistent substance may imply exposure, but exposure to a non-hazardous substance can never be equated to risk or potential harm. The PFAS Proposal thus uses proxies for risk and harm that have not been validated, neither in general nor in the case of PFAS.

The reasoning developed in the PFAS Proposal does not meet the rigor required by the scientific method and flunks the requirements imposed by the REACH Regulation's restrictions regime. There is no showing of any "unacceptable risk" that is "not adequately controlled" for the vast majority of PFAS. The extreme precautionary approach advocated by the draftsmen conflicts with the available data on many of the PFAS substances and makes a mockery of the conditions for both regulating chemical risk and applying the precautionary principle.

2) From presumed persistence to presumed harm

In consecutive steps, the proponents progressively move away from the REACH restrictions regime's requirements and conditions towards free-floating chemical regulation unrestrained by science or law. These steps include:

- A shift from risk (which is the basis of the REACH restrictions regime) to hazard (which is used for purposes of classification) based on a precautionary assumption that a hazard, upon exposure (however defined), will present a risk.

- A shift from hazard as defined under the CLP and REACH Regulations (which set specific criteria) to a "hazard" that is not defined under these regulations.

- A move from actual, proven hazard to "potential hazard," which is hazard that may be found to exist in the future.

- A shift from undefined, potential hazard to emission as a proxy for exposure, thus turning potential hazard into actual risk.

- Finally, a claim to authority to regulate risk in the absence of hazard based on fear of potential future harm.

Thus, in the PFAS universe of the proponents, presumed persistence becomes presumed harm warranting regulation. Consequently, while still paying lip service to science and law, the proponents of the PFAS Proposal operate entirely beyond the realm of science-based risk regulation and the REACH restrictions regime.

4. Conclusions

Most of the shortcomings of the PFAS proposal arise from the lack of a scientific basis and disregard for rigorous methodology and legal standards, masquerading as creative regulatory interpretation to enhance the level of protection consistent with the precautionary principle.

There is little or no science to support the proposed ban. The methodology that has been employed to patch together the PFAS proposal is scientifically indefensible. In relation to the vast majority of PFAS substances falling within the proposal's scope, the REACH Regulation's condition of "unacceptable risk" is not met. If the proposal were adopted as is, it would constitute a poor and counterproductive policy.

a. Novel regulatory concepts

The proponents seem to believe that they are free to 'freewheel' based on the novel regulatory concepts suggested in the Commission's Chemicals Strategy for Sustainability, such as the generic approach to risk management, undisciplined grouping, use of invalid proxies, and broad bans softened by 'essential use' exemptions, even though these concepts are not yet mature, controversial and, importantly, not part of the current legislative framework governing the risk management decision that is to be made.[391] Many of the fundamental propositions set out in the PFAS proposal are inconsistent with both the available science and the provisions of the REACH Regulation, specifically, the REACH restrictions regime; it is the REACH Regulation that should govern, not the proponents' imaginary regulatory regime.

Indeed, as discussed throughout this paper, the reasoning laid out in the PFAS proposal is based on a series of propositions the validity of which has not been demonstrated. One such proposition is the use of a descriptive definition of PFAS developed by the OECD that is not intended for regulatory purposes. This definition is invoked to subject an open-ended group of substances, including approx. 10,000 chemicals currently in commerce and an indefinite number of substances that do not yet exist, to restrictions that have not been shown to be justified by the risks posed by the vast majority of the substances falling within the proposal's scope. This definition is the cornerstone of a grouping approach inspired by a concern for "regrettable substitution" and the lack of "efficiency" of substance-by-substance regulation in accordance with the REACH Regulation, which effectively results in the circular argument that 'PFAS are a group because they pose the same hazard, and PFAS share the same hazard because they are a group.'

[391] Cf. ERIF, Novel Regulatory Philosophies – Future Directions and Implications for Risk Management, Highlights Note 21, March 2023.

b. Assuming the legislative standards away

The proponents assume, but do not even attempt to prove, that all substances falling within the scope of their proposal are persistent; persistence alone, however, does not make a substance hazardous. As they admit, there simply are no substance-specific data available for the vast majority of PFAS substances covered by the proposed ban. Any showing of bioaccumulation or toxic effects is absent for these substances. Nowhere do the proponents explain how there can be risk, let alone unacceptable risk, if there is no hazard. The grouping approach employed by the proponents is based on radical, lobsided precautionary thinking, not on scientific evidence, and ignores both the lack of necessity of regulating the vast majority of PFAS substances and the costs of regulating of substances that have not been shown to pose any risk in the real world.

Emissions of PFASs from manufacture and use (including in products) are deemed to be unavoidable because "end-of-pipe solutions" (and apparently all other emission minimization measures) are "not achievable,"[392] but no persuasive evidence supporting this proposition is made available. The proponents insist on addition and combined effects of PFASs based on the hypothesis that "many" PFAS "exhibit similar effects,"[393] and justify their choice with reference to "precautious" "worst case scenario estimation,"[394] without providing adequate empirical evidence to support this thesis.

According to the proponents of the ban, emissions are an adequate proxy for risk and harm, based on the proposition that "due to the persistence of PFASs, the environmental stock will continue to grow both in the EU and globally," which "leads to a growing risk of negative environmental and health impacts and, thus, damage over time,"[395] even though no causal link between emissions and any risks has been established for the vast majority of PFASs falling within the scope of the proposal. Insofar as the covered PFAS substances meet the REACH criteria, persistence alone is not a hazard and definitely not a risk; it is a much-desired property, durability, in many instances. Alleged "uncertainty,"[396] which is invoked to justify the idea that any detectable presence of PFAS should be banned, is neither a scientific reason nor a legal justification for banning substances that have not been shown to pose any risk.

c. Unlawful use of derogations

Apparently, the proponents assume that proposal's overly broad scope can be mitigated lawfully by establishing a derogations regime based on some sort of notion of "essential

[392] Annex XV Restriction Report, PFASs, 22 March 2023, p. 2.
[393] Annex XV Restriction Report, PFASs, 22 March 2023, p. 32.
[394] Annex XV Restriction Report, PFASs, 22 March 2023, p. 32.
[395] Annex XV Restriction Report, PFASs, 22 March 2023, p. 49.
[396] "Estimation of future exposure levels and safe concentration limits is highly uncertain." Annex XV Restriction Report, PFASs, 22 March 2023, p. 37.

use," which is not even part of the current legislation and ignores the REACH Regulation's requirement that the substances subject to restriction be identified.[397] While the REACH Regulation in addition to substance-by-substance regulation, accommodates, under strict conditions, a grouping approach, it does not permit that an overly broad group be corrected through derogations at the regulators' discretion.

d. Prioritizing false negatives over false positives

The precautionary approach adopted for purposes of the PFAS proposal afflicts the scientific assessment not only of the risks of PFAS substances, but also of the alternatives and the related risk/risk tradeoffs inherent to the proposed bans. Analysis of the impacts and risks of the PFAS proposal itself is rudimentary at best, while the benefits are inflated.

The PFAS Proposal is based on the idea that any Type II error (a false negative), i.e. a substance that is hazardous but not included in the PFAS proposal, should be prevented at the expense of an enormous number of Type I errors, i.e. false positives, or substances that are not hazardous but fall within the scope of the proposal. This is precautionary thinking gone seriously awry.

The precautionary principle should be applied also to the measures to address any risk targeted by regulators (risk/risk trade-offs[398]) – if that had been done, it would have become clear that the actual risks of the broad bans imposed by the proposal would be very serious (including, for instance, safety risks), and exceed the theoretical risks of many of the PFAS substances falling within the scope of the proposal.

e. Unlawfully imposing biodegradability

From a risk governance perspective, the proponents apparently believe they are free to find risk in the absence of hazard and to require that substances effectively be biodegradable, i.e., non-persistent. However, there is no authority to be found in the REACH Regulation, or any other EU law for that matter, for such regulation. The suggestion in the Commission's Recommendation on an assessment framework for 'safe and sustainable by design' chemicals that all substances be "fully biodegradable for uses that unavoidably lead to release into the environment or wastewater"[399] cannot justify the imposition of a disguised biodegradability requirement on 10,000 substances and many more that will never be.

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[397] Due to the heavy reliance of the derogations program with reversal of the burden of proof, the PFAS proposal resembles an authorization regime disguised as a restriction, which raises a question as to whether this regime would meet the REACH standards for the authorization regime or those applying to the restriction regime.

[398] Cf. John D. Graham & Jonathan Baert Wiener, Risk vs. Risk: Tradeoffs in Protecting Health and the Environment, Harvard University Press, 1997.

[399] European Commission, Annex to Recommendation establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials, C(2022) 8854 final, Brussels, 8.12.2022, p. 5, https://research-and-innovation.ec.europa.eu/document/download/2c78478d-b493-48c4-9bc9-f97464d22b6f_en

If chemicals are to be banned in the absence of risk and required to be biodegradable, such a far-reaching decision would have to be made by the EU legislature, not by regulators with little accountability. On this ground alone, if the PFAS restriction were enacted as is, it is unlikely to survive judicial review.[400] In addition, the EU legislature should be involved in the decision-making, because, as discussed,[401] the restriction would violate fundamental rights and principles of law.

f. Lack of effectiveness

There is also reason to doubt the effectiveness of an EU-only ban. The proponents merely assume that an EU PFAS ban will have a significant effect on the environmental concentration of PFAS globally, even though such a ban will merely move the production and use of PFAS to non-EU jurisdictions and will not result in any significant reduction of PFAS in the global environment.[402]

g. Adverse and counterproductive effects of the proposed ban

Consistent with the promise of the "toxic-free society" the proponents suggest that public health and environmental protection would be served in the long term by the proposed PFAS restriction, even though the health and environmental risks associated with the restriction of PFAS may be immediate and serious; for instance, the ban may well increase safety risks in relation to medical applications of PFAS and malfunctioning sealants at installations handling hazardous substances.

No evidence or even reasoned argument is presented to the effect that the benefits of the proposal outweigh the costs, and both of the proposed risk management options are assumed to be proportional despite the unreliability of the data on the costs of PFAS, which the proponents acknowledge. Moreover, there is a virtual absence of sound data on the cost of restricting and phasing out many PFAS.

From a public policy perspective, the proposed PFAS restriction, insofar as its widespread impacts can currently be assessed, will likely have very serious adverse effects on the economy, innovation, and investment, while the health and environmental benefits, due to regrettable substitution, will be negligible, if not negative. The EU apparently believes that it can stimulate innovation by converting the open incentive-based approach to innovation (patents) into a closed disincentive-based approach (bans only loosely based on weak science), which replicates only a necessary condition for innovation but fails to appreciate other necessary and sufficient conditions.

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[400] Standing to bring an action against the PFAS restriction is an issue, but there appear to be applicants that have standing before the European courts. Cf. Bergkamp, L. (2016). Private Party Standing and EU Risk Regulation: Expanded Standing Rights in the Public Interest. European Journal of Risk Regulation, 7(3), 557-568. doi:10.1017/S1867299X00006073

[401] See Section 3.a.v, above.

[402] Kevin C Jones, Persistent Organic Pollutants (POPs) and related chemicals in the global environment: some personal reflections, Environ. Sci. Technol. 2021, 55, 14, 9400–9412, https://doi.org/10.1021/acs.est.0c08093 ("emissions from one country are frequently a source of contamination to another country").

h. Taking better regulation seriously

Viewed from a regulatory perspective, the PFAS Proposal represents excessive "smorgasbordism" that would risk further deindustrialization of the European Union. The EU already has several regulatory instruments in place to regulate the known hazards and risks posed by substances falling within the scope of the PFAS proposal.[403]

These regulations could be amended, as necessary, to address any risks that need to be regulated. Putting a broad ban on top of all existing other regulations addressing risks posed by PFAS substances is unwarranted and contrary to the EU better regulation approach.[404]

i. Managing uncertainty

Often under the guise of scientific uncertainty or precaution, a plethora of subjective value judgments are reflected in the PFAS proposal. Each of the assumptions and propositions invoked to support the broad PFAS ban can be challenged and demonstrated to be false or at least questionable.

The fundamental misconception underlying the PFAS proposal is that a theory of uncertainty of knowledge, which morphs into fear of potential future harm, can justify regulation. Any such theory, however, is not based on rigorous scientific methodology and data, but on precautionary generalizations and wishful, motivated reasoning from a few data points.[405] It inevitably disregards formal legal requirements.[406]

j. The false promise of the "toxic-free society"

The proposed PFAS ban is illustrative of a broader set of problems that plague risk regulation. It would set a precedent the EU should want to avoid, as it would not bode well for the upcoming revision of the REACH Regulation. After all, the PFAS restriction proposal

[403] As discussed, PFOS and PFOA, for instance, are already regulated. See further Section 2.a, above.
[404] COMMISSION STAFF WORKING DOCUMENT, Better Regulation Guidelines, Brussels, 3.11.2021 SWD(2021) 305 final, https://commission.europa.eu/system/files/2021-11/swd2021_305_en.pdf
[405] C. L. Berry, Relativism, regulation and the dangers of indifferent science: The Sir Roy Cameron lecture of the Royal College of Pathologists, Toxicology, Vol. 267, Issues 1–3, 2010, pp. 7-13, https://doi.org/10.1016/j.tox.2009.11.005, https://www.sciencedirect.com/science/article/pii/S0300483X09005812 ("the Precautionary Principle is a good example of only considering results that fit a preconceived viewpoint.")
[406] Majone, G. (2010). Foundations of Risk Regulation: Science, Decision-Making, Policy Learning and Institutional Reform. European Journal of Risk Regulation, 1(1), 5-19. doi:10.1017/S1867299X00000027 Cf. Vecchione, E. (2011). Science for the Environment: Examining the Allocation of the Burden of Uncertainty. European Journal of Risk Regulation, 2(2), 227-239. doi:10.1017/S1867299X00001173 PASKALEV, V. (2020). The Clash of Scientific Assessors: What the Conflict over Glyphosate Carcinogenicity Tells Us about the Relationship between Law and Science. European Journal of Risk Regulation, 11(3), 520-538. doi:10.1017/err.2020.59

casts doubt on the desirability of the open-ended 'generic approach' to risk management and the 'essential use' concept.[407]

Fundamentally, the EU Green Deal's "toxic-free" society is a false promise and, as the analysis presented above has demonstrated, the PFAS ban is a prime example. The ban's proponents can claim that it will increase the level of protection only by making assumptions about hypothetically avoided future harms and ignoring actual current risk arising from the ban for which they advocate. Naturally occurring PFAS, however, should have given the ban's proponents a hint that there is more to this issue.[408]

The proposed PFAS restriction fails to meet the requirements of sound science and of science-based regulation pursuant to the REACH Regulation and would likely do more harm than good.

Society cannot and should not be toxic-free.[409] Likewise, society cannot be free of PFAS, and if it wants to be safe, it should not want to be free of PFAS.

k. Back to the drawing board

The EU should go back to the drawing board, since the PFAS proposal that is currently going through public consultation misses the mark on all fronts: science, law, and policy.

A regulatory proposal that is aimed narrowly at reducing the known unacceptable risks of specific PFAS substances to acceptable levels is what science-based chemical risk governance and the REACH Regulation require.[410]

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[407] Chemicals: Commission seeks views on revision of REACH, the EU's chemicals legislation, Jan. 20, 2022, available at https://environment.ec.europa.eu/news/chemicals-commission-seeks-views-revision-reach-eus-chemicals-legislation-2022-01-20_en

[408] Kevin C Jones, Persistent Organic Pollutants (POPs) and related chemicals in the global environment: some personal reflections, Environ. Sci. Technol. 2021, 55, 14, 9400–9412, https://doi.org/10.1021/acs.est.0c08093 ("Most are man-made, but some also have natural origins. They are persistent in the environment, but they can be broken down variously by biodegradation, atmospheric reactions, and abiotic transformations.") Harlov, D.E., Aranovich, L. (Eds.), The Role of Halogens in Terrestrial and Extraterrestrial Geochemical Processes Surface, Crust, and Mantle, Springer, 2018. Gribble, G.W., A recent survey of naturally occurring organohalogen compounds. Environmental Chemistry, 2015, http://dx.doi.org/10.1071/EN15002 Gribble, G.W., The diversity of naturally occurring organobromine compounds. Chemical Society Reviews, 1999, 28: 335–346.

[409] Cf. Matthias Herzler et al. (German Federal Institute for Risk Assessment, BfR), The "EU chemicals strategy for sustainability" questions regulatory toxicology as we know it: is it all rooted in sound scientific evidence?, Archives of Toxicology (2021) 95:2589–2601, https://doi.org/10.1007/s00204-021-03091-3 For further discussion, see Frank A. Barile, et al., The EU chemicals strategy for sustainability: in support of the BfR position, Archives of Toxicology, 2021, https://doi.org/10.1007/s00204-021-03125-w For a similar critical analysis, see James W. Bridges, Helmut Greim, Kees van Leeuwen, Rainer Stegmann, Theo Vermeire, Klaas den Haan, Is the EU chemicals strategy for sustainability a green deal?, Regulatory Toxicology and Pharmacology, Volume 139, 2023, 105356, https://doi.org/10.1016/j.yrtph.2023.105356, https://www.sciencedirect.com/science/article/pii/S0273230023000247

[410] As we recommended in 2003, "t]he European Union should consider alternative regulatory approaches, such as the exposure-oriented approach." L. Bergkamp & J.C. Hanekamp, The draft REACH regime: costs and benefits of precautionary chemical regulation, Environmental Liability 2003, pp. 167-180.