


REPORTS

One Step Closer to Zero Chemical Pollution: The Legal Adoption and Implications of the Per- and Polyfluoroalkyl Substances Restriction Proposal

Viktorija Obolevich 

Department of Law, Aarhus University, Aarhus, Denmark
Email: vao@law.au.dk

Abstract

This paper focuses on the legal adoption and possible implications of the proposed per- and polyfluoroalkyl substances (PFAS) restriction. In the case of PFAS, this restriction puts value on the regulatory efforts to implement far-reaching and ambitious targets amid a high level of scientific uncertainty. The purpose of this paper is to present a report rather than conducting an in-depth analysis of the mentioned field. Overall, the paper argues that such a daring decision might be justified by the precautionary principle. However, the implementation might raise opposition from the stakeholders' side and might take longer than initially anticipated, most likely with additional derogations concerning essential goods that do not currently have safe alternatives.

Keywords: Ban; PFAS; precautionary principle

I. Introduction

On 13 January 2023, Denmark, Germany, the Netherlands, Norway and Sweden submitted a dossier to the European Chemicals Agency (ECHA) proposing new restrictions aimed at significantly reducing the introduction of per- and polyfluoroalkyl substances (PFAS) into the environment.¹

PFAS, also known as “forever chemicals”, are a group of chemical substances that serve a wide range of customer needs and are used in the production of almost everything – textiles, food packaging, cosmetics, medical devices, electronics and many other products. These chemical substances are known for their high persistence in the environment, degradation resistance, high accumulation potential (in water, animals, plants and human bodies), mobility and long-distance transportability and global warming and (eco) toxicological effects.² In recent decades, scientific studies have determined that the presence of some PFAS in the environment is linked to harmful health effects in humans and animals.³ However, for the majority of PFAS present in the environment, such data are still missing or are scarce.

¹ ECHA, “ECHA receives PFASs restriction proposal from five national authorities” <<https://echa.europa.eu/de/-/echa-receives-pfass-restriction-proposal-from-five-national-authorities>> (last accessed 29 August 2023).

² ECHA, Annex XV Restriction Report: Proposal for a Restriction, March 2023, p 22.

³ For more details, see H Brunn et al, “PFAS: forever chemicals – persistent, bioaccumulative and mobile” (2023) 35 Environmental Sciences Europe 20.

The PFAS proposal was drafted pursuant to Article 68 of the REACH Regulation⁴ and proposes to restrict more than 10,000 PFAS. It claims to be one of the most comprehensive bans in the European Union's (EU) chemical history.⁵ The proposed restrictions are currently undergoing a scientific review and a six-month stakeholder consultation process. It could be several years before they take effect.

The proposal applies to the entire supply chain, and the proposed restrictions will have major impacts on manufacturers, distributors and end users in the EU and beyond. Products containing PFAS will need to be redesigned or even discontinued. It means that dozens of products as we know them, such as Teflon pans, waterproof clothes, dental floss, water-repellent cosmetics, microwave popcorn bags and many others that contain PFAS, will be removed from or replaced in our daily lives.

According to the dossier submitters, the best option to avoid PFAS emissions is to prohibit the manufacture and use of PFAS to the greatest extent possible.⁶ That is also why the proposed regulatory options are leaving little room for manoeuvre. The proposal presents two regulatory options. The first option includes a total ban on PFAS⁷ after a limited eighteen-month transition period, and the second option includes a similar ban and transition period with some time exemptions for certain categories of PFAS. More precisely, the second option includes an eighteen-month transition period plus either a five- or twelve-year derogation period. Both options are aimed at almost complete PFAS elimination and would result in a need to radically rethink the production, design and usage of products that we use on a daily basis.

Public concern about the legacy of PFAS is growing and has already attracted a great deal of attention throughout the European media,⁸ and this is expected to be a speculative and hot topic over the next few years. In addition to the main question of whether this proposed restriction is appropriate and proportionate to reduce health and environmental risks and socio-economic impacts, it also casts a shadow over previous regulations and has bewildering repercussions: if regulators have known for years that PFAS are harmful, why was the initiative for this restriction not taken earlier? And, in contrast, if PFAS are not so hazardous, should they be completely banned?

The presence of so many PFAS in our environment is intimidating and has pushed regulators to take immediate action to prevent their catastrophic environmental effects, although it might already be too late to act. In this case, the precautionary principle might be engaged in its full capacity and applied using an extrapolation approach for the thousands of PFAS that still present a lack of evidence regarding their hazardous effects.

The goal of this paper is prospective, and it aims to present an overview rather than conducting a detailed analysis of the mentioned field.

The rest of the paper is structured as follows: Section II focuses on the complications in defining PFAS. Section III assesses the legal background to the mentioned proposal. Section IV examines whether the PFAS proposal fulfils the requirements of the precautionary principle. Section V discusses the possible outcomes and the challenges that industries will face if the proposal is adopted. Section VI concludes the paper.

⁴ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

⁵ ECHA, *supra*, note 1.

⁶ ECHA, *supra*, note 2, 76.

⁷ Including mixtures and substances containing PFAS above a certain concentration. ECHA, *supra*, note 2, 2.

⁸ For example, regarding Denmark, see <<https://www.dr.dk/nyheder/indland/partier-vil-forbyrde-pfas-her-kan-du-moede-det-i-din-hverdag-og-her-er-det-allerede>>; <<https://www.dr.dk/nyheder/indland/supermarkedsgigant-gaar-til-kamp-mod-pfas-stoffer-i-stegepander>>; regarding Germany, see <https://www.welt.de/newsticker/dpa_nt/infoline_nt/politik_ausland_nt/article243642781/Ewige-Chemikalien-sollen-in-EU-beschraenkt-werden.html>; and regarding France, see <https://www.lemonde.fr/en/les-decodeurs/article/2023/02/23/forever-pollution-explore-the-map-of-europe-s-pfas-contamination_6016905_8.html> (all last accessed 29 August 2023).

II. PFAS definition

Due to the complexity and diversity of PFAS, it is a difficult task to characterise and categorise them coherently and consistently, and, currently, there is no universal definition of PFAS.

Several governmental and non-governmental groups have developed their own chemical structure-based PFAS definitions for regulatory and non-regulatory purposes. However, these definitions are not comprehensive and might raise ambiguities in interpretation.⁹ For example, a widely used definition of PFAS, provided by Buck et al,¹⁰ excludes aromatic compounds,¹¹ whereas compounds with similar structures but without aromatic rings are recognised as PFAS. This tiny difference might create confusion, especially for non-experts.

In 2021, the Organisation for Economic Co-operation and Development (OECD) tried to solve this problem and offered a broadly inclusive PFAS definition and practical guidance.¹² This definition provides a starting point to the bigger picture of the PFAS universe, including the option that users may define their own working scope of PFAS for specific purposes. It expands the Buck et al definition to a much wider range of substances, and it includes PFAS from “small molecules, to more complex aromatics with a perfluorinated methyl/methylene group on the side chain(s), to diverse polymers”.¹³

The dossier submitters echo the OECD definition, and the restriction proposal covers all uses of PFAS, unless there is a specific derogation. It is a quite broad and general definition, meaning that thousands of PFAS fall into this category. The dossier submitters argue that such a wide scope of restriction was necessary to prevent the substitution of one type of PFAS by another.¹⁴ In recent years, there were incidents in which PFAS that had previously been proven dangerous were replaced by other PFAS whose effects are still unknown.¹⁵

However, some scholars find the broad OECD definition problematic and express concern that if the regulators will use it, it may present implications for the pharmaceutical industry and other producers of organofluorine chemicals.¹⁶ The use of the OECD definition might imply the banning of dozens of pharmaceuticals, including essential ones, such as the cancer drug alpelisib, the SARS-CoV-2 drug Paxlovid and the top prescribed antidepressant Prozac.¹⁷

It is important that a PFAS definition is formulated using specific and non-ambiguous language and is explicit in describing the context for which a definition is applied. Moreover, if a broad PFAS definition is considered, it may be useful to make derogations for specific uses based on the context of the definition (eg for certain types of organofluorines).

⁹ E Hammel et al, “Implications of PFAS definitions using fluorinated pharmaceuticals” (2022) 25(4) *iScience* 104020.

¹⁰ RC Buck et al, “PFAS in the environment: terminology, classification, and origins” (2011) 7(4) *Integrated Environmental Assessment and Management* 513–41.

¹¹ Structures containing unsaturated hydrocarbon rings with double and single bonds.

¹² OECD, *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance* (2021) <[https://one.oecd.org/document/ENV/CBC/MONO\(2021\)25/En/pdf](https://one.oecd.org/document/ENV/CBC/MONO(2021)25/En/pdf)> (last accessed 7 September 2023).

¹³ Z Wang et al, “A New OECD Definition for PFAS” (2021) 55(23) *Environmental Science & Technology* 15575–78.

¹⁴ ECHA, *supra*, note 2, 1.

¹⁵ L Parkinson, “Regrettable substitution & the precautionary principle” (*Food Packaging Forum*, 6 September 2022) <<https://www.foodpackagingforum.org/food-packaging-health/regrettable-substitution-the-precautionary-principle>> (last accessed 29 August 2023).

¹⁶ Hammel et al, *supra*, note 9.

¹⁷ *ibid.*

III. Legal background

Despite increasing attention and the growing extent of the regulation of chemicals in Europe, the regulation of chemicals in Europe is far from optimal, as some researchers claim “current chemical regimes are not just suboptimal but seriously inadequate”.¹⁸ The Chemicals Strategy for Sustainability (CSS), which aims to achieve the EU’s zero pollution target, a key commitment of the European Green Deal, particularly emphasises that PFAS require special attention, and it asks for “a comprehensive set of actions to address the use of and contamination with PFAS”.¹⁹

Some PFAS are already regulated through the EU REACH Regulation on chemical substances²⁰ and the EU’s Persistent Organic Pollutants (POPs) Regulation.²¹ For example, the POPs Regulation restricts the manufacture, placing on the market and use of perfluorooctane sulphonic acid (PFOS) and perfluorooctanoic acid (PFOA), as well as their salts and related compounds. In February 2023, under REACH, the EU restriction on the use of perfluorocarboxylic acids containing nine to fourteen carbon atoms in the chain (C9–C14 PFCAs) and their derivatives came into force.

Article 68(1) of REACH states that new restrictions, introductions and amendments of current restrictions can be made only when there is an unacceptable risk to human health or the environment. In addition, any such decision shall take into account the socio-economic impact of the ban, including the availability of alternative chemicals.

In most instances, a chemical must be proven dangerous to be removed from the market.

The PFAS definition does not imply that all PFAS have the same properties, exposures, uses and, most importantly, risks.²² It means that the term “PFAS” does not denote automatically that the substance is hazardous. The key hazardous element common to all PFAS on which the dossier submitters build their restriction argument is the high persistence of PFAS. This high persistence is viewed as sufficient reason for banning PFAS as a chemical class. Persistence is generally perceived as having fewer and no obvious hazardous effects; however, it leads to irreversible environmental effects. Several scientists argue that the planetary boundary of PFAS contamination has already been exceeded²³ and that regulation of PFAS based on persistence alone should be sufficient.²⁴

Not all PFAS are equally harmful,²⁵ and the proposal submitters admit the presence of a large number of uncertainties in the proposed restriction of so many chemical substances.²⁶ The proposal does not demonstrate that each and all of them present an unacceptable risk. Considering that PFAS are a large and complex group of chemicals with various chemical and physical properties, it might be quite problematic to assess and

¹⁸ E Millstone and P Clausing, “Reasons for Reinforcing the Regulation of Chemicals in Europe” (2023) 14(1) *European Journal of Risk Regulation* 78–92.

¹⁹ EC, *Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment*, 667 final (2020), section 2.2.3, p 13.

²⁰ REACH, *supra*, note 4.

²¹ Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

²² OECD, *supra*, note 12, 25.

²³ IT Cousins et al, “Outside the Safe Operating Space of a New Planetary Boundary for PFAS” (2022) 56(16) *Environmental Science & Technology* 11172–79.

²⁴ For example, see IT Cousins et al, “The high persistence of PFAS is sufficient for their management as a chemical class” (2020) 22(12) *Environmental Science: Processes & Impacts* 2307–12; M Scheringer et al, “Stories of Global Chemical Pollution: Will We Ever Understand Environmental Persistence?” (2022) 56(24) *Environmental Science & Technology* 17498–501.

²⁵ PFAS Free Project, Fidra <<https://www.pfasfree.org.uk/about-pfas/pfas-science-the-basics>> (last accessed 29 August 2023).

²⁶ ECHA, *supra*, note 2, 187.

present the risk of the substances individually, and the most feasible solution,²⁷ which the dossier submitters also use, is to adapt the generalisation, simplification and extrapolation approach, without going into detailed scrutiny. The dossier submitters follow the Green Deal's advice – “one chemical, one assessment”²⁸ – and apply the precautionary approach for groups of chemicals, and they do not perform a substance-by-substance risk control assessment.

Nevertheless, the most convenient solution for regulators might not be the best option for stakeholders.

IV. The precautionary principle

The precautionary principle, one of the fundamental legal principles of environmental law, allows regulators to act despite scientific uncertainty.

Its classical definition from 1992 outlines that “where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation”.²⁹ Case law has added to that, stating that precautionary actions cannot be introduced relying purely on hypothetical risk – such actions can be taken only when it is adequately, if not fully, supported by scientific evidence,³⁰ and, at the same time, cases stress that it is important to “take protective measures without having to wait until the obviousness and severity of those risks become fully apparent”.³¹ Under the conditions of high uncertainty and a lack of scientific evidence, this draws a very thin line for regulators between acting and non-acting – specifically, whether to take precautionary measures or to refrain from them. The EU Communication from the Commission on the precautionary principle³² tries to clarify the application of this legal principle and prescribes that, in order to apply it, the measures should be proportionate to the chosen level of protection, non-discriminatory in their application and consistent with similar measures already taken. Furthermore, they should be based on an examination of the potential benefits and costs of action or a lack of action and be subject to review in the light of new scientific data. Finally, they must be capable of assigning responsibility for producing the scientific proof necessary for a detailed risk assessment.³³

Does the PFAS proposal fulfil the requirements of the precautionary principle?

1. Proportionality and examination of potential benefits and costs

For its part, the dossier submitters have done their utmost and presented the environmental and socio-economic impacts of the proposed restriction options assessed for the fourteen sectors in which the largest amounts of PFAS are used and emitted. The analysis includes economic impacts on manufacturers and customers, the enforcement and certification costs of public authorities and human health and

²⁷ European Environment Agency, “Emerging chemical risks in Europe – ‘PFAS’” (2019) <<https://www.eea.europa.eu/publications/emerging-chemical-risks-in-europe>> (last accessed 7 September 2023); see also P Grandjean, “Delayed discovery, dissemination, and decisions on intervention in environmental health: a case study on immunotoxicity of perfluorinated alkylate substances” (2018) 17 Environmental Health 62.

²⁸ ECHA and EFSA, “In support of the EU chemicals strategy for sustainability: one substance – one assessment” (2020) <<https://www.efsa.europa.eu/en/corporate/pub/osoa>> (last accessed 7 September 2023).

²⁹ UN, Rio Declaration on Environment and Development (1992), Principle 15.

³⁰ Case T-13/99, Pfizer [2002] EU:T:2002:209, para 143; see also Case C-236/01, Monsanto Agricoltura [2003] EU:C:2003:431, para 106; Case C-192/01 Commission v Denmark [2003] EU:C:2003:492, para 49; Case C-41/02, Commission v Netherlands [2004] EU:C:2004:762, para 52.

³¹ Pfizer, supra, note 30, para 139.

³² EC, “Communication from the Commission on the Precautionary Principle” (2000) <<https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:en:PDF>> (last accessed 7 September 2023).

³³ *ibid.*, 3.

environmental impacts. However, the dossier submitters themselves conclude that, for most sectors, a proportionality assessment is not feasible³⁴ and the social costs cannot be predicted.³⁵ At the same time, their conclusion is based on the belief that the restriction offered by the first regulatory option could be proportionate in the medium and long term because the social costs linked to continued use of PFAS will likely increase and ultimately exceed the costs caused by a ban on the use of PFAS.³⁶ In turn, the restriction plan offered by the second option would balance the trade-offs between short-term (causing less drastic economic impacts on society in the short term and giving the necessary time for the adjustment and replacement of PFAS in comparison to the first option) and long-term (the societal costs of continued PFAS use) impacts. Suitable alternatives are claimed to be available for many of PFAS.³⁷

Although a direct assessment of proportionality has not been possible, the dossier submitters believe that the proposed ban is proportionate to the risk, as the social costs linked to continued use of PFAS will progressively increase and will exceed the costs caused by a ban.

2. Non-discrimination and consistency with similar measures

The proposal aims for uniform application within the EU, meeting the non-discrimination criterion. At the same time, as mentioned above, some PFAS are already regulated, and the proposal might be seen as a continuation of already existing EU measures that regulate hazardous chemicals. Nevertheless, if implemented, it could be one of the most ambitious chemical regulation efforts in the history of the EU.

3. Review based on new scientific data

Science regarding PFAS is evolving, and for most of the PFAS present in the environment relevant scientific data are still missing. Such a sweeping ban highlights the large amount of uncertainty surrounding the scale of the problem, the extent of risk and whether the proposed ban would contribute to societal benefit. Further research on this risk and analysis of safer alternatives would be needed. As regulatory bodies are scrutinising PFAS more closely, we can expect more new scientific data to emerge in the near future.

Overall, the proposal falls under the requirements of the precautionary principle. Nevertheless, it should be noted that the precautionary principle cannot be a rigid regulatory instrument, and that decision-makers should be asked to carefully reflect on context as well as new scientific data.³⁸ Industries will likely strive to present new scientific data regarding PFAS in the next half-year in an attempt to decrease the scope of restrictions.

V. Possible outcomes

Some stakeholders claim that the PFAS proposal is endorsed more by politics than science and does not consider essential uses, variations in the subgroups of PFAS, disruptions of supply chains and the provision of sufficient transition time for industries. Traditional science demands strong evidence; however, the precautionary approach asks us to be

³⁴ ECHA, *supra*, note 2, 180.

³⁵ *ibid*, 190.

³⁶ *ibid*, 191.

³⁷ *ibid*.

³⁸ RECIPIES, “Guidance on the application of the precautionary principle in the EU” (2022) p 7 <https://www.ecologic.eu/sites/default/files/publication/2022/2814_RECIPES_Guidance_Book_final.pdf> (last accessed 7 September 2023).

cautious when we are in doubt³⁹ and allows for the implementation of restrictions amid high uncertainty.

It might be challenging for industries to follow the broad restrictions and remove PFAS from the entire supply chain. The dossier submitters believe that, although the proposed ban is broad, the “manageability of it is sufficiently practical”.⁴⁰

However, the proposed restrictions could raise opposition from stakeholders, who might try to delay and decrease the extent of the proposed restrictions.⁴¹ Moreover, under the second regulatory option, this might represent an additional burden to manufacturers and importers of PFAS, who would still be using PFAS during the allowed time period, because they would be required to present an annual report detailing the basis of their derogations and clarifying the types and quantities of used PFAS. Manufacturers, importers and downstream users would be required to establish site-specific management plans that would include information on the identity of the substances and the products used, provide a justification for their use and provide details on the conditions of use and safe disposal.⁴²

The complete ban on so many PFAS might create large disturbances within many industries. It could be that many industries still do not know how they will be affected. The stakeholder consultation could reveal more issues that the regulators should consider, and the implementation of the restriction might take longer than anticipated.

VI. Conclusions

Overall, the PFAS restriction proposal might be justified by the precautionary principle. However, it might raise opposition from the stakeholders’ side, more evidence is expected and some derogations might be added stemming from the ambiguous PFAS definition.

The dossier submitters present the most pessimistic scientific concerns regarding the hazardous nature of PFAS and, despite a high level of uncertainty, apply a holistic approach for phasing them out. Some PFAS are already regulated, and this ban, if implemented, would bring about an almost complete end to PFAS, pushing stakeholders to be more innovative in searching for safer PFAS alternatives. Perhaps some products will disappear from the market, which, if the definition of PFAS is not refined, might include some essential pharmaceuticals.

Remarkably, such comprehensive restrictions might represent a brave shift from strong evidence-based policies to precautionary-based policies, where the principle “better safe than sorry” is pursued. The proposal might pave the way for long-lasting effective change in the regulation of chemicals that spread across the world. Consequently, such an exhaustive ban on PFAS might bring the world one step closer to zero chemical pollution.

Acknowledgments. This article is written within the Regulating Emerging Pollutants project that is supported by the Carlsberg Foundation, grant number CF19-0170. The author would like to particularly thank Associate Professor Katerina Mitkidis and the anonymous peer reviewer for their helpful comments. The usual disclaimer applies.

Competing interests. The author declares none.

³⁹ *ibid.*, 9.

⁴⁰ ECHA, *supra*, note 2, 181.

⁴¹ Corporate Europe Observatory, “Chemical romance: how politicians fell for BASF” (15 March 2023) <<https://corporateeurope.org/en/chemical-romance-politicians-basf>> (last accessed 29 August 2023).

⁴² ECHA, *supra*, note 2, 8.