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Editorial

On 7 February 2023, the European Chemicals Agency (ECHA) published the long-waited restriction proposal on per- and polyfluoroalkyl substances (PFAS) under the REACH Regulation, as submitted by 5 Member States of the European Economic Area, namely Germany, the Netherlands, Denmark, Sweden and Norway. Some regard it as the most complex initiative to restrict the manufacture, use and placing on the market of a group of chemicals in the history of the European Union. The proposal will now follow the regulatory procedure established under REACH articles 69 through 73 for adopting restrictions. Following a 6-month public consultation, the Risk Assessment Committee (RAC) and the Socio-Economic Assessment Committee (SEAC) of ECHA will develop their opinons (with an additional 2-month public consultation on the SEAC opinion). After that, the European Commission will provide a draft amendment to the list of restrictions in Annex XVII of REACH. The final decision will be taken in comitology procedure with scrutiny involving the Member States and the European Parliament.

Following the definition used, the restriction is expected to cover approximately 10,000 synthetic substances, based on the carbon-fluorine bond, related to the presence in a substance of fully fluorinated methyl (-CF3) or methylene (-CF2-) groups, with a few exceptions. With such a broad scope, it is likely that the impact on the European industry of a possible restriction on PFAS will be significant, particularly since the proposal does not differentiate between substances that may have different toxicity profiles; indeed, the justification to launch a restriction on PFAS as a group is based on 'persistency and other concerns' related to these chemicals, and the fact that previous initiatives to regulate PFAS chemicals individually has resulted in substitution of one PFAS molecule by another molecule that also matches the PFAS definition, and may exhibit similar toxicological properties.

With the increasing interest in the regulation on PFAS in both the scientific and regulatory community, Tiffany Thomas and her co-authors analyse the different regulatory actions that have been launched both in Europe and in the United States of America, including federal and state-level initiatives. An exhaustive list of different pieces of legislation is provided and described with detail to demonstrate how regulators have approached the concerns around PFAS from different perspectives.

Fluoropolymers stand out as a differentiated sub-group within the PFAS family. They are regarded as Polymers of Low Concern following definitions by the OECD. Fluoropolymers are high value materials that enable the adequate functioning of a number of key industrial sectors in Europe. While focus on fluoropolymer applications has been traditionally looked from the perspective of users by consumers, Jaime Sales and co-authors describe how the benefits of fluoropolymer use stand out more clearly when linked to industrial sectors, on the basis of their contribution to safety, decarbonisation, circularity and outstanding overall performance.

Continuing on the fluoropolymer case, Bruno Ameduri and colleagues describe the initiatives that the manufacturers of these materials have taken over the years to remove one of the main concerns highlighted by regulators around PFAS, which is the use of fluorinated polymerization aids (surfactants) in the manufacturing process of fluoropolymers. A non-exhaustive list of patents issued in the XXI Century is described (initiatives date back as far as the 1960s) to find commercially viable non-fluorinated surfactants), and the significant progress achieved from certain producers of fluoropolymers is highlighted, which should significantly contribute to removing PFAS emissions from the fluoropolymer supply chain.

We hope you enjoy this special issue of ICRL and encourage you to submit your own work for future issues of the journal.

Dieter Drohmann
Managing Editor

Global Regulations Around PFAS: The Past, the Present and the Future

*Tiffany Thomas, Adel Malek, Jude Arokianathar, Elie Haddad and Joanna Matthew**

Per- and polyfluoroalkyl substances (PFAS) have been gaining global public and regulatory attention for several years. Their widespread use across various sectors, coupled with mounting research on their inherent persistent, bioaccumulative, and/or toxic properties, has prompted action to significantly decrease or eliminate PFAS manufacture and use. This article provides detailed analyses of the key global regulatory instruments that have shaped and may shape the future of PFAS use in our society. It details the European Union's (EU) approaches with those adopted in the United States of America (USA) (at federal and state levels) with a focus on a comparative evaluation of the regulatory regimes and initiatives. The current outlook and impact of the Stockholm Convention on Persistent Organic Pollutants are also discussed in this article. This report informs on the future of PFAS regulation, and how pending legislation might shape the commercial and industrial markets.

I. Introduction

PFAS are a growing global concern and have captured the media and public spotlight due to a growing body of scientific data demonstrating environmental persistence and negative human health impacts.[1] Consequently, phasing out the production and use of PFAS have become a priority in many parts of the regulatory world.

The key global players, the EU and USA, are making significant inroads towards minimising the manufacture, import, sale, and use of PFAS. However, due to the decades long and widespread use of PFAS across numerous industry sectors and commercial applications, complete elimination from the marketplace is a challenge especially due to their instrumental role in the functionality and performance of many products.[2] Alternatives for PFAS are not currently available for many applications and, in some cases, research and development of viable replacements may take several years.[3] However, some primary PFAS manufacturers have started withdrawing from the marketplace. For example, 3M Corporation, the inventors of PFOA and major manufacturers of PFAS in the USA, announced on 20 December 2022 that they would cease manufacture of PFAS by the end of 2025.[4]

With the recent publication of the EU REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) PFAS restriction proposal on 7 February 2023, the EU's PFAS regulatory approach is likely to enter into force in 2025 and become effective the following year. In the restriction proposal, various time-limited derogations have been proposed based on essential uses and the current lack of suitable alternatives.[5] At present, the USA has not instituted an analogous blanket restriction, but rather a series of targeted bans specific to certain applications or products, some only enacted in select

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1 Interstate Technology and Regulatory Council, 'PFAS Fact Sheets' (2022) <https://pfas-1.itrcweb.org/fact-sheets/> accessed 30 March 2023.

2 Environ. Sci.: Processes Impacts, 2019,21, 1803-1815.

3 Environ. Sci.: Processes Impacts, 2019,21, 1803-1815.

4 3M, '3M to Exit PFAS Manufacturing by the End of 2025' (2022) <https://news.3m.com/2022-12-20-3M-to-Exit-PFAS-Manufacturing-by-the-End-of-2025> accessed 5 April 2023

5 Annex XV Restriction Report Proposal For A Restriction Substance Names(s): Per- and polyfluoroalkyl substances (PFASs), Version 2, 7 February 2023.

states.[6] Regulations in the USA and states therein are a patchwork of actions targeting use restriction, disposal practices, and maximum drinking water levels.

Herein, we present the existing global PFAS regulatory framework, the status of promulgated and proposed regulatory actions, and compare the fundamental differences between the varying approaches.

II. Regulations in the EU

1. Existing EU Regulations

Current regulatory oversight in Europe is in force for a subset of PFAS chemicals through the following set of regulations.

a. EU Persistent Organic Pollutants (POPs) Regulations

With an aim to restrict or eliminate the production, use, import, and export of POPs, the United Nations' Stockholm Convention on POPs is a global treaty that came into effect in 2004.[7] The EU's commitments to the treaty are implemented through Regulation (EC) No 850/2004 (the 'POPs Regulation'). Specific PFAS are listed as "New POPs" in the Stockholm Convention List.[8]

In 2009, perfluorooctane sulfonic acid (PFOS), its salts, and perfluorooctane sulfonyl fluoride (PFOS-F) were the first set of PFAS restricted for use through listing in Annex I of the EU POPs regulation imposing limits in substances and articles.[9] In 2020, amendments to Annex I removed all exemptions for PFOS use in the EU (e.g., metal plating and photoimaging).[10] In 2019, perfluorooctanoic acid (PFOA), its salts, and related compounds (PFOA) were added to Annex A of the Stockholm Convention. Since 2020, their use has been banned under (EU) 2020/784 amendment of the EU POPs regulation.[11] Exceptions include laboratory research use as reference standard or if these substances are unintentional contaminants [0.001 percent (%) by weight (wt.) for PFOS, 0.0000025% by wt. for PFOA].

b. REACH Regulation

The broad REACH regulation governs the manufacture, import, and sale of chemical substances in Europe.[12] Under REACH, PFAS are restricted or prohibited through inclusions in the Substance of Very High Concern (SVHC) Candidate List as substances meeting criteria laid out by Article 57 of REACH or through listing on Annex XVII.

SVHC placement is based on persistence, mobility, and toxicity properties that pose threats to human and ecological health following environmental exposures. Three groups of PFAS have been added to the SVHC Candidate List in June 2019, January 2020, and January 2023. Group 1 includes 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts, and its acyl halides (HFPO-DA, also known as GenX chemicals). Group 2 includes perfluorobutane sulfonic acid (PFBS) and its salts; and Group 3 includes perfluoroheptanoic acid (PFHpA) and its salts.

PFAS placement on the SVHC Candidate list is due to their identification of equivalence concerns as carcinogenic, mutagenic and reprotoxicants (CMRs) and persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBTs/vPvBs) chemicals. The SVHC listing also mandates additional legal obligations if articles bear the concerned substances at concentration >0.1% by wt. These include duty to

6 Interstate Technology and Regulatory Council, 'PFAS Fact Sheets' (2022) <https://pfas-1.itrcweb.org/fact-sheets/> accessed 30 March 2023.

7 The Stockholm Convention on Persistent Organic Pollutants, opened for signature May 23, 2001, UN Doc. UNEP/POPS/CONF/4, App. II (2001), reprinted in 40 ILM 532 (2001).

8 See, <http://chm.pops.int/TheConvention/ThePOPs/TheNewPOPs/tabid/2511/Default.aspx> accessed 1 May 2023.

9 Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (recast) (Text with EEA relevance.) PE/61/2019/REV/1.

10 COMMISSION DELEGATED REGULATION (EU) 2020/1203 of 9 June 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the entry for perfluorooctane sulfonic acid and its derivatives (PFOS) (Text with EEA relevance)

11 COMMISSION DELEGATED REGULATION (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds. (Text with EEA relevance)

12 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

communicate information to customers on safe use (Article 33 REACH) and notification to the European Chemicals Agency (Article 7-2 REACH).

Certain PFAS are also listed in the REACH Annex XVII Restricted Substances List. In 2021, perfluorocarboxylic acids [which contain 9 to 14 carbon atoms in the chain (C9-C14 PFCAs)], their salts and related substances were added to the list.[13] Since 25 February 2023, the manufacture, use, and sale of these substances have been banned except if the concentration in the substance, the mixture, or the article is below 25 parts per billion (ppb) for the sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCA-related substances.

For Annex XVII listing, provisions for deferrals and overall exemptions have been put into place to address specific sectors' issues. Beginning in July 2023, restrictions will be enforced in areas such as oil- and water-repellent textiles used for personal protective equipment (PPE). Certain uses are permitted until July 2025, such as photolithography or etch processes in semiconductor manufacturing. Additional sectors where use is permitted until July 2025 include photographic coatings applied to films; implanted medical devices; and firefighting foam for Class B fires (with the caveat that use will only be allowed on sites where all releases can be contained). Additional exemptions and details on the transition period are listed in the Annex of the amendment.[14]

13 Commission Regulation (EU) 2021/1297 of 4 August 2021 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards perfluorocarboxylic acids containing 9 to 14 carbon atoms in the chain (C9-C14 PFCAs), their salts and C9-C14 PFCA-related substances (Text with EEA relevance)

14 Ibid Annex XVII

15 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance)

16 See, <https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/european-union.htm> accessed 2 April 2023

17 DIRECTIVE 2013/39/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy (Text with EEA relevance)

18 Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast) (Text with EEA relevance)

c. The Classification, Labelling and Packaging (CLP) Regulation

- These regulations first came into effect in 2009 to align the European system for the management of chemicals with the United Nations' Globalized Harmonized System.[15] The PFAS included in the Classification and Labelling Inventory include PFOA, ammonium pentadecafluorooctanoate (APFO), perfluorononan-1-oic acid (PFNA) and its sodium and ammonium salts, nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts, and PFHpA.
- Legally binding in member states, the CLP regulation sets detailed criteria around identifying and classifying hazards and communicating to all entities in the supply chain (including consumers) to protect handlers, users, and the environment. An essential component of CLP includes classification and labelling to ensure appropriate risk management strategies are implemented for hazards posing the most severe concerns (such as carcinogenicity, mutagenicity, and CMR). The Organization for Economic Cooperation and Development (OECD) maintains a current list of PFAS and their respective classifications.[16]

d. Drinking Water Directive

- This Directive is the EU's main legal instrument concerning the access to and quality of water intended for human consumption. In 2013, under Directive 2013/39/EU, PFOS and its listed derivatives were included as priority substances in the field of water policy.[17] The revised Drinking Water Directive (2020) established a 'new group limit' value for 'PFAS Total' of 0.5 μg/L or the limit for the 'Sum of PFAS' of 0.1 μg/L in drinking water.[18] The Directive entered into force in 2021 and permitted member states a two-year transition period for incorporation into National legislation. EU countries are exempt if water use is intended exclusively for purposes for which authorities are satisfied that quality has no influence, either directly or indirectly, on consumer health.

e. Prior Informed Consent (PIC) Regulations

In the EU, the PIC regulations implement the mandates of the Rotterdam Convention. They came into effect in 2014 aiming at promoting international co-operative efforts towards environmentally sound movement and usage of hazardous chemicals.[19] PFOA (and its salts and derivatives) and PFOS (and its salts and derivatives) were listed in Annex I as chemical substances under export notifications under limitation categories of "sr-b" (severe restriction-ban) and "sr" (severe restriction) respectively.

f. Member state specific regulations

In May 2020, Denmark promulgated Order No. 681 'Executive Order on Food Contact Materials and Penal Code for Violation of Related EU Acts' to prohibit PFAS use in food contact materials (FCMs).[20] In effect from July 2020, under the provisions of this law, paper and cardboard FCMs are not permitted for sale. However, PFAS use is exempted in FCMs if a functional barrier exists in the products to effectively prevent migration to food. In 2014, Norway became the first country to ban the use of PFOA in consumer products.[21]

Verification of compliance and enforcement of EU-level regulations falls under the jurisdiction of national authorities (the specifics of which are beyond the scope of this review).

2. Emerging EU regulations

a. EU PFAS Restriction Proposal

On 7 February 2023, the European Chemicals Agency (ECHA) revealed a major legislative step towards the phaseout of PFAS – the EU REACH PFAS restriction proposal ("wide-use restriction"). This restriction, which will cover all PFAS uses (except firefighting foams), will work in tandem with the EU PFAS restriction for firefighting foams to mark the end for many PFAS uses across various sectors and applications.[22] The wide-use restriction is likely to become effective as early as 2026 with the eventual view of banning all PFAS uses, although the timeline will depend on the progress made with the restriction proposal.

i. Scope

The wide-use restriction proposal aims to restrict the manufacture, sale, and use of PFAS, either as themselves, or as constituents in other substances, mixtures or articles. These restrictions apply above certain concentration thresholds for both non-polymeric and polymeric PFAS as described in Table 1 (Appendix).

As anticipated, the proposal implements the OECD definition for PFAS as *"any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it)."*[23]

The dossier submitters of the proposal state that at least 10,000 PFAS will fall under the definition's scope, although the OECD's Comprehensive Global Database of PFAS covers only 4,730 PFAS.[24] Some fully degradable PFAS subgroups are included in their estimate of PFAS covered. As these subgroups do not satisfy the high persistence criteria inherent with many PFAS, these substances are excluded from the scope of the restriction proposal.

Within the scope of the PFAS definition, fluorinated gases (F gases), which are commonly used as refrigerants, and fluoropolymers, which are used across numerous key industrial applications, are included. There has been some debate whether these substances should be included as part of the restriction. For example, under standard conditions of use, fluoropolymers are not expected to degrade to other highly persistent PFAS, or potentially toxic substances.[25,26]

The proposal does, however, provide full derogations (no time limit) for certain uses, including:

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19 REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals (recast) (Text with EEA relevance)

20 Order on food contact materials and on penalties for infringements of related EU legal acts, BEK no. 681 of 25/05/2020

21 Environmental Agency of Norway Regulation FOR-2013-05-27-550

22 ANNEX XV RESTRICTION REPORT PROPOSAL FOR A RESTRICTION SUBSTANCE NAME(S): Per- and polyfluoroalkyl substances (PFASs), Version Number 2, 22 March 2023.

23 Environ. Sci. Technol. 2021, 55, 23, 15575–15578

24 See, <https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/> accessed 3 April 2023

25 Sales, J. , Hernández, F. , Kapoor, D. , & van den Noort, M. Fluoropolymers: The Safe Science That Society Needs International Chemical Regulatory and Law Review Volume 5, Issue 1 (2022) pp. 13 - 23

26 Korzeniowski, S.H., Buck, R.C., Newkold, R.M., kassmi, A.E., Laganis, E., Matsuoka, Y., Dinelli, B., Beauchet, S., Adamsky, F., Weilandt, K., Soni, V.K., Kapoor, D., Gunasekar, P., Malvasi, M., Brinati, G. and Musio, S. (2023), A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. Integr Environ Assess Manag, 19: 326-354.

- active substances in biocidal products within the scope of Regulation (EU) 528/2012;[27]
- active substances in plant protection products within the scope of Regulation (EC; European Commission) 1107/2009;[28] and
- active substances in human and veterinary medicinal products within the scope of Regulation (EC) No 726/2004,[29] Regulation (EU) 2019/6,[30] and Directive 2001/83/EC.[31]

However, the manufacturers and importers of these substances must submit certain information (e.g. substance identity and quantity of substance placed on the market) to ECHA every two years. For other (time-limited) derogations, the reporting period is one year.

ii. Options

The essential use concept, which is to be clarified in accordance with the Chemicals Strategy for Sustainability (CSS), is not included in the wide-use PFAS proposal.[32,33,34,35] This concept will establish the uses:

- critical for health and safety and for society to function; and
- where no viable alternatives are present.

Despite no specific mention or implementation of this concept, there are a few full derogations established as specified above. The proposal also provides room to potentially accommodate further derogations that are use-specific and time-limited. From this, as given in Table 2 (Appendix), two restriction options (ROs) are put forward for consideration for the wide-use PFAS restriction.

ECHA has highlighted certain uses that will be reconsidered for derogation following the Annex XV report consultation, which commenced on 22 March 2023 for a 6-month period. Additionally, other derogations will also be considered, where a strong case is put forward by stakeholders.

b. Additional Draft EU PFAS Legislation

i. EU PFAS Restriction Proposal for Firefighting Foams

The PFAS restriction proposal for firefighting foams, which will restrict the formulation, marketing, and use of all PFAS-containing firefighting foams following any derogation periods (use- or sector-specific), paved the way for the wide-use PFAS restriction proposal.[36] The firefighting foam proposal is likely to enter into force in 2025.

ii. REACH, POPs and CLP Regulations

There are various emerging PFAS regulatory actions under the REACH, POPs and CLP Regulations, including:

- REACH restriction proposals for perfluorohexane-1-sulphonic acid (PFHxS), its salts and related substances, and undecafluorohexanoic acid (PFHxA), its salts and related substances;[37]
- Inclusion of PFHxS, its salts and related compounds under the POPs Regulation in line with the Stockholm Convention;[38] and

27 REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products

28 REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

29 REGULATION (EC) No 726/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

30 REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC

31 DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 6 NOVEMBER 2001 ON THE COMMUNITY CODE RELATING TO MEDICINAL PRODUCTS FOR HUMAN USE Official Journal L – 311, 28/11/2004, p. 67 – 128, and subsequent amendments.

32 European Commission, Directorate-General for Environment, Bougas, K., Flexman, K., Keyte, I., et al., Supporting the Commission in developing an essential use concept: final report, Publications Office of the European Union, 2023.

33 Environ. Sci. Technol. 2022, 56, 10, 6232–6242

34 Environ. Sci.: Processes Impacts, 2021,23, 1079-1087

35 M. Guenther, H. The Essential or Critical Use of Chemical Substances in the United States and the European Union International Chemical Regulatory and Law Review Volume 5, Issue 1 (2022) pp. 3 - 12

36 ANNEX XV RESTRICTION REPORT PROPOSAL FOR A RESTRICTION SUBSTANCE NAME(S): Per- and polyfluoroalkyl substances (PFASs) in firefighting foams, Version 2.0, 23 March 2022

37 ANNEX XV RESTRICTION REPORT PROPOSAL FOR A RESTRICTION SUBSTANCE NAME(S): Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related substances Version 1.1, 13 June 2019

38 Ref. Ares(2023)958923 - 09/02/2023 Amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorohexane sulfonic acid (PFHxS), its salts and
PHFxS-related compounds

- 3,3,4,4,5,5,6,6,7,7,8,8,8-Tridecafluorooctan-1-ol (6:2 FTOH) consideration for inclusion into the CLP Regulation.[39]

iii. EU Member States

In addition to the EU PFAS restriction proposals for firefighting foams and all other uses of PFAS, certain member states are planning to take legislative action to restrict PFAS in certain products:

- Belgium has proposed to prohibit the placing on the market of packaging containing PFAS from 1 January 2024;[40]
- Denmark is preparing for a ban on PFAS contained in firefighting foams used in training sites from 1 January 2024;[41] and
- France published an action plan on 17 January 2023, which provides guidance on protecting the French people and environment from risks associated with PFAS.[42]

It should be noted that following the UK's exit from the EU, it has implemented several EU regulations such as the POPs, REACH, CLP and PIC regulations.[43,44,45,46] Recently, the Health and Safety Executive (HSE) published a report on the regulatory management options (RMOA).[47] This is the first step towards the UK PFAS restriction proposal, which will fall under the UK REACH regulation and is expected to be closely aligned with the EU proposal.

III. North America Regulations – Federal and State

1. Existing Regulations

Existing USA federal regulations affecting the general public have primarily fallen under the oversight of the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), while actions specific to defence personnel, operations, installations, and their immediate surroundings are administered by the Department of Defence (DoD). Similarly, various states have promulgated independent regulatory actions under the state equivalent of the EPA. Canadian regulations are overseen by Environment and Climate Change Canada (ECCC) and its provincial offices. Mexico's Ministry of Environment has not yet regulated PFAS. Where in place, the existing regulations have focused on the following:

a. Consumer products

Beginning in 2016, the FDA banned the use of long-chain PFAS in FCMs.[48] A review of short-chain substitutes is underway for other consumer product applications under the New Chemicals Program of the Toxic Substances Control Act (TSCA), overseen by the EPA.[49] Several states, including California[50], Maine[51], Maryland[52], Minnesota[53], Oregon[54], and Washington[55], have banned the use of PFAS in spe-

39 CLH report Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2 International Chemical Identification: 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol Version 2, January 2021

40 Draft Royal Decree to limit the placing on the market of single-use products harmful to the environment and to increase the recycled content of certain products, 2022/827/B (Belgium), 29/11/2022 <https://ec.europa.eu/growth/tools-databases/tris/index.cfm/en/search/?trisaction=search.detail&year=2022&num=827&mLang=EN> accessed 1 May 2023.

41 See, <https://mim.dk/nyheder/2023/jan/pfas-forbud-oevelsespladser-doorstep/> accessed 5 April 2023

42 See, <https://www.ecologie.gouv.fr/sites/default/files/22261_Plan-PFAS.pdf> accessed 5 April 2023.

43 2019 No. 1340, EXITING THE EUROPEAN UNION, ENVIRONMENTAL PROTECTION The Persistent Organic Pollutants (Amendment) (EU Exit) Regulations 2019 14 October 2019

44 See, <https://www.hse.gov.uk/reach/index.htm> accessed 5 April 2023

45 The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019, Number 720

46 See, <https://www.hse.gov.uk/pic/> accessed 5 April 2023

47 Analysis of the most appropriate regulatory management options (RMOA), Substance Name: Poly- and perfluoroalkyl substances (PFAS), UK Health and Safety Executive, March 2023

48 United States Code of Federal Regulations (CFR) 81 CFR 5, January 4, 2016; 81 CFR 83672, November 22, 2016

49 See, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/new-chemicals-program-review-alternatives-pfoa-and> accessed 3 April 2023

50 California Code of Regulations (CCR) Title 22 Division 4.5 Ch 55, Art 11, Section 69511.4; HEALTH AND SAFETY CODE – HSC DIVISION 20. MISCELLANEOUS HEALTH AND SAFETY PROVISIONS [24000 - 26275] CHAPTER 6.6. Safe Drinking Water and Toxic Enforcement Act of 1986 [25249.5 - 25249.14] (Proposition 65) for PFOA and PFOS

51 Maine Public Law c. 277 An Act To Protect the Environment and Public Health by Further Reducing Toxic Chemicals in Packaging

52 Maryland HB0275/ SB0273 Environment – PFAS Chemicals – Prohibitions and Requirements (George "Walter" Taylor Act)

53 Minnesota (MN) Statute 325F.075 FOOD PACKAGING; PFAS

54 Oregon Revised Statutes 431A.253 to 431A.280 Toxic-Free Kids Act

55 Revised Code of Washington 70A.222 Prohibition on the manufacture, sale, or distribution of certain food packaging

cific consumer goods. State bans most commonly reference FCM and carpet treatments. The ECCC has banned the manufacture, use, sale, and import of PFOS, PFOA, long-chain (C9-C20) PFCAs, and their collective salts and precursors.[56]

b. AFFF Use and Purchase

The National Defence Authorization Act (NDAA) of 2020 enacted a series of congressional mandates regarding the transition from AFFF to a fluorine-free foam (F3) alternative.[57] Products meeting the new military specifications (MILSPEC) must be made available to all DoD bases by 1 October 2023, and AFFF foam use will be prohibited after 1 October 2024.[58] The Federal Aviation Administration (FAA) has signalled that F3 products approved by the DoD will be similarly acceptable for use in commercial aviation applications.[59]

Multiple states have already instituted bans on the use of AFFF for training and non-emergency purposes, or strictly control the use, storage, and disposal of AFFF. Alaska, Arizona, California, Colorado, Georgia, Illinois, Indiana, Louisiana, Michigan, New Hampshire, Washington, and Wisconsin have enacted variations of laws to this effect.[60,61,62,63,64,65,66,67,68,69,70]

The ECCC has banned the use of AFFF with a few exemptions allowing for overseas military operational considerations and to accommodate efforts to transition to F3.[71] As of 21 June 2019, the Canadian Aviation Regulations were amended to allow all Canadian airport operators to use International Civil Aviation Organization International Standards and Recommended Practices performance specifications in lieu of CAN/ULC-S560.[72]

c. Drinking water

At this time, there are no federally regulated drinking water standards in the USA. The EPA has established a series of Regional Screening Levels (RSLs) for PFOA, PFOS, PFNA, PFBS, PFHxS, and HFPO-DA, which are applicable to groundwater.[73] Note that the RSLs are not promulgated rules and are, therefore, not legally enforceable limits under statute.

A number of states have independently adopted regulatory standards for drinking water in the absence of federal criteria utilising a variety of programmes, and include: Massachusetts, Michigan, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and Washington.[74] Typically targeting PFOA and PFOS limits are

56 See, <https://www.canada.ca/en/environment-climate-change/services/management-toxic-substances/list-canadian-environmental-protection-act/perfluorooctane-sulfonate/film-forming-foam-prohibition-toxic-substances.html> accessed 2 April 2023

57 National Defense Authorization Act for Fiscal Year 2020, S.1790 - 116th Congress (2019-2020)

58 United States Department of Defence MIL-PRF-32725 Performance Specification: Fire Extinguishing Agent, Fluorine-Free Foam (F3) Liquid Concentrate for Land-Based, Fresh Water Applications, 6 January 2023

59 Federal Aviation Administration National Part 139 CertAlert: New Military Specification for Performance-Based Standards for Fluorine-Free Aircraft Fire Fighting Foam. 12 January 2023

60 Alaska Statutes (AS) Title 46.03.826(5), AS 46.09.900(4), Alaska Administrative Code 18 AAC 75.300 - Discharge or release notification; reporting requirements

61 Arizona Senate Bill 1526 - AN ACT AMENDING TITLE 36, CHAPTER 13, ARIZONA REVISED STATUTES, BY ADDING ARTICLE 9; RELATING TO FIREFIGHTING FOAM REGULATION.

62 California Senate Bill 1044 - An act to add Sections 13029, 13061, and 13062 to the Health and Safety Code, relating to fire protection.

63 Colorado House Bill 19-1279 - Protect Public Health Firefighter Safety Regulation PFAS Polyfluoroalkyl Substances Concerning the use of perfluoroalkyl and polyfluoroalkyl substances, and, in connection therewith, making an appropriation.

64 Georgia House Bill 458 to amend Chapter 2 of Title 25 of the Official Code of Georgia Annotated

65 Illinois Public Act 102-0290 – PFAS Reduction Act

66 Indiana Code (IC) 36-8-10.7 – Public Safety

67 Louisiana Act No. 232 to enact Louisiana Revised Statute Title 40 Public Health and Safety

68 Michigan (HB 4389), An ACT to amend 1966 PA 291

69 New Hampshire Revised Statutes 154:8-b and 154:8-c Certain Chemicals Prohibited in Firefighting Foam

70 Revised Code of Washington 70A.400 FIREFIGHTING AGENTS AND EQUIPMENT—TOXIC CHEMICAL USE

71 See, <https://www.canada.ca/en/environment-climate-change/services/management-toxic-substances/list-canadian-environmental-protection-act/perfluorooctane-sulfonate/film-forming-foam-prohibition-toxic-substances.html> accessed 2 April 2023

72 Exemption from paragraph 323.08(1)(a) of the Aircraft Fire Fighting at Airport and Aerodromes Standards made pursuant to section 303.08 of the Canadian Aviation Regulations; NCR-035-2018; 21 June 2019.

73 See, <https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables> accessed 1 May 2023.

74 Values summarized, with regulatory references, on the ITRC website for convenience. See, <https://pfas-1.itrcweb.org/fact-sheets/> accessed 3 April 2023

equal to or less than 70 parts per trillion or nanograms per litre (ppt) (with some exceptions). Some of the listed states also have promulgated standards for one or more additional PFAS analytes under either drinking water or groundwater statutes. Due to the evolving nature of these programmes, the authors strongly recommend verifying the regulatory status in a given jurisdiction at regular intervals.

Canada has not promulgated a national drinking water standard for PFAS. Alberta, however, has promulgated a set of maximum allowable concentrations for PFOA and PFOS of 200 ppt and 600 ppt respectively as an ambient water quality guideline for drinking water sources.[75]

d. Hazardous Substance

At present, the EPA has not listed any PFAS chemical as a hazardous substance under a federal programme. However, the NDAA of 2020 included a directive to list 172 PFAS to the Toxics Release Inventory. As a result, suppliers of products containing listed PFAS are required to update the Safety Data Sheets accordingly. Alaska, Massachusetts, New Jersey, New York, and Vermont have independently listed PFOS and PFOA, and possibly additional PFAS, as hazardous under state programmes.[76,77,78,79,80] The inclusion of PFOS, PFOA and other PFAS as hazardous chemicals triggers numerous other regulatory actions promulgated within the given jurisdiction, specifically waste management and disposal practices.

2. Emerging regulations

In October 2021, the USA EPA published the *PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024*.[81] The document outlines a series of 31 specific actions spanning EPA's regulatory purview. These actions were designed to be implemented at varied timelines representing both finite and ongoing activities. Key unresolved action items include the following:

- **Establish a national primary drinking water regulation for PFOA and PFOS:** Under the Safe Drinking Water Act, the EPA announced a series of draft Maximum Contaminant Levels (MCLs) on 14 March 2023 for the following PFAS: PFOA at 4.0 ppt, PFOS at 4.0 ppt, and a mixture of PFNA, PFHxS, PFBS, and HFPO-DA with a combined Hazard Index of 1.0.[82] The MCL represents the maximum allowable concentration of these analytes in public drinking water. These proposed values have entered into a public comment period and are expected to be met with resistance from a number of stakeholders.
- **Restrict PFAS discharges from industrial sources and leverage the National Pollutant Discharge Elimination System (NPDES) permits to reduce PFAS discharges to waterways:** In December of 2022, the EPA issued a guidance memo to states permitting sections with recommendations on permit restrictions and monitoring requirements.[83] It remains unclear as to the extent to which the state programmes will implement the stated guidance.
- **Designate PFOA and PFOS as hazardous substances under Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA):** In August 2022, the EPA formally proposed the designation of PFOA and PFOS as CERCLA hazardous substances.[84] If listed, a variety of

75 Alberta Tier 1 Soil and Groundwater Remediation Guidelines, AEP, Land Policy, 2022, No. 4; ISBN: 978-1-4601-5501-1, 1 January 2023

76 Alaska Statutes (AS) Title 46.03.826(5), AS 46.09.900(4), Alaska Administrative Code 18 AAC 75.300 - Discharge or release notification; reporting requirements

77 Code of Massachusetts Regulations Title 310 Section 40.0000 Massachusetts Contingency Plan

78 New Jersey Statutes Annotated 58:10-23.11 Spill Compensation and Control Act

79 New York Codes, Rules, and Regulations Title 6 Part 375 Environmental Remediation Programs

80 INVESTIGATION AND REMEDIATION OF CONTAMINATED PROPERTIES RULE STATE OF VERMONT AGENCY OF NATURAL RESOURCES DEPARTMENT OF ENVIRONMENTAL CONSERVATION WASTE MANAGEMENT AND PREVENTION DIVISION Emergency Rule, 11 July 2018 and updates

81 PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024, United States Environmental Protection Agency. EPA-100-K-21-002, October 2021.

82 ENVIRONMENTAL PROTECTION AGENCY 40 CFR Parts 141 and 142 [EPA–HQ–OW–2022–0114; FRL 8543–01– OW] RIN 2040–AG18 PFAS National Primary Drinking Water Regulation Rulemaking

83 Addressing PFAS Discharges in NPDES Permits and Through the Pretreatment Program and Monitoring Programs, Memorandum to EPA Regional Water Division Directors, Regions 1-10, US EPA, 5 December 2022.

84 ENVIRONMENTAL PROTECTION AGENCY 40 CFR Part 302 [EPA–HQ–OLEM–2019–0341; FRL–7204–02–OLEM] RIN 2050–AH09 Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances, 6 September 2022.

regulatory triggers would follow, including: due diligence during real estate transactions would require evaluation for PFOA and/or PFOS, regulatory agencies could seek cost recovery from potentially responsible parties that contribute to PFOA and/or PFOS, and the National Priority List (Superfund) programme would be expanded to include sites contaminated by PFOA and/or PFOS.

At the state level, an extensive list of 182 legislative actions is pending in 32 states as of March 2023.[85] These regulations span a variety of topics, including:
- Bans on PFAS-containing fire-fighting substances;
- Bans on PFAS in commercial products, FCMs, menstrual products, cosmetics, stain and water-resistant treatments, and pesticides;
- Mandates to remove and replace AFFF systems from fire departments; and
- Mandates to monitor and/or treat wastewater system and landfill leachate for PFAS.

Due to the evolving nature of these programmes, verifying the regulatory status in a given jurisdiction at regular intervals is recommended.

In July 2022, the Mexican Ministry of Environment proposed to restrict the import and export of PFOA and PFOS.[86] Opinions have been submitted but the current status of the regulation is unknown.

IV. Other Global Regulations

1. Australia

Australian governments have developed regulatory, policy, and voluntary approaches for import, use, waste disposal, and remediation. Australia has also assessed the risks of more than 200 PFAS available for use in Australia, with a focus on PFOS and PFOA and their precursors.[87,88] The risks of shorter chain PFAS that may be used as replacements for PFOS and PFOA have also been assessed.

The 2018 Intergovernmental Agreement on a National Framework for Responding to PFAS Contamination is an agreement between the Australian Government and state and territory governments to respond consistently to PFAS contamination.[89] A position statement sets out the view of the Australian governments that use of PFAS should be limited to the greatest extent practicable and lists objectives for phasing-out the use of PFAS of concern in Australia.

Importers and manufacturers of PFAS must comply with the obligations of the Industrial Chemicals Act 2019 (IC Act) that came into force on 1 July 2020.[90] Obligations include registering the business with the Australian Industrial Chemicals Introduction Scheme (AICIS) and categorising new PFAS before they can lawfully introduce these chemicals into Australia. AICIS also enforces import and export controls on PFOS and specified PFOS precursors that are subject to the PIC procedure under the Rotterdam Convention. Three jurisdictions (South Australia, Queensland, and New South Wales) have restricted the use of certain PFAS in firefighting foams. South Australia was the first state to ban all PFAS-containing firefighting foams; the ban came into effect on 30 January 2018.[91]

The January 2020 PFAS National Environmental Management Plan (NEMP) sets out standards and guidance, which includes investigation guideline values.[92] The PFAS NEMP promotes flexible implementation of best practice and is a practical how-to guide for the investigation and management of PFAS contamination, including waste management, storage and disposal.

2. New Zealand

New Zealand's Environmental Protection Authority published new restrictions on 21 December 2022 for

85 See, <https://www.saferstates.org/bill-tracker/> accessed 30 March 2023

86 AGREEMENT MODIFYING THE MISCELLANEOUS WHICH ESTABLISHES THE GOODS WHOSE IMPORT AND EXPORT IS SUBJECT TO REGULATION BY THE DEPENDENCIES THAT MAKE UP THE INTERSECRETARIAT COMMISSION FOR THE CONTROL OF THE PROCESS AND USE OF PESTICIDES, FERTILIZERS AND TOXIC SUBSTANCES, 03/0049/150722

87 Industrial Chemicals Act 2019, No. 12, 2019, Compilation No. 3, 6 November 2021

88 See, <https://www.industrialchemicals.gov.au/consumers-and-community/and-poly-fluorinated-substances-pfas> accessed 1 May 2023.

89 Intergovernmental Agreement on a National Framework for Responding to PFAS Contamination Council of Australian Governments, 20 February 2018.

90 Industrial Chemicals Act 2019, No. 12, 2019, Compilation No. 3, 6 November 2021

91 South Australia Environment Protection (Water Quality) Policy 2015 under the Environment Protection Act 1993, Version 1.7.2020

92 PFAS National Environmental Management Plan, National Chemicals Working Group of the Heads of EPAs Australia and New Zealand, Version 2.0, 2020

AFFF.[93] Effective from 1 January 2023, the use of firefighting foams containing PFAS in uncontained systems has been prohibited. The prohibition applies to AFFF that contain PFOA-related compounds. New Zealand plans a complete ban on PFAS-containing firefighting foams after 3 December 2025.

3. Asia

Several countries in Asia are moving to restrict and manage use of PFAS (mostly PFOA, PFOS, and PFHxS) in accordance with the Stockholm Convention on POPs, including China, Japan, and South Korea. In addition, in March 2023, China added PFOA and PFOS to its List of New Pollutants for Priority Management to manage/restrict their production, use, import, and export.[94] In October 2022, Japan and South Korea enacted new export requirements for PFOA. In January 2021, South Korea announced its 3rd Basic Plan (2021-2025) for management of POPs that includes developing standards and analytical procedures and elimination technologies for PFAS.[95]

4. Other Countries

At present, 152 countries have ratified the Stockholm Convention, which puts in place elimination and restriction of listed PFAS with exemptions for specific uses such as hard metal plating firefighting foams. As of 5 April 2023, the USA, Malaysia, Israel, Haiti, and Brunei Darussalam have not ratified the convention. Although ratified, there is no indication that a number of the member nations have made efforts to regulate PFAS via other independent mechanisms.

V. Comparative Analyses and Implications on Industry

As mentioned above, a significant overhaul in PFAS regulatory oversight is ongoing or expected shortly in several countries and regions. The EU PFAS restriction proposal is the most stringent and broadly scoped legislation heavily impacting multiple industry sectors. The EU intends to avoid substance-by-substance evaluation as a regulatory risk management option for this large and complex group of chemicals. By imposing restrictions on the entire PFAS group, the PFAS proposal has major aims to prevent in-kind substitutions (replacement of one PFAS by another) and significantly reduce the manufacture, use and entry of any PFAS or their breakdown products into the environment. The proposal covers 15 industrial sectors ranging from consumer products and electronics to petroleum, construction, and medical applications (Section 1.3.2-Annex XV restriction report). Currently in the post-publication consultation phase (six-month period starting March 2023), the proposal presents two options following transition periods after entry into force as outlined in Table 2; a complete ban (RO1) or with use-specific time-limited derogations (RO2: 0, 5 or 12 years of derogation dependent on the status of alternative options and their supply availability). New uses are also subject to conditions imposed by this proposal. In certain areas such as defence or the cement industry, authorities are engaging with stakeholders to obtain specific information on alternative substitutions, status of research and development, and resultant socioeconomic impacts (Table A.1 of Annex A of Annex XV restriction report).

In contrast, the USA has focused regulatory attention on drinking water concentrations, with a limited number of bans on PFAS use in specific product types. Regulatory actions have targeted specific PFAS through regulatory instruments and initiatives such as the 2023 Draft National Drinking Water Standards (March 2023), Inactive PFAS Significant New Use Rule (January 2023), Proposal to enhance reporting of PFAS data to TRI (December 2022), Proposed Hazardous Substances designation for PFOA and PFOS (2022), and PFAS Strategic Roadmap (2021-2024). In addition to the EPA, several USA states have also been actively involved in regulating PFAS more stringently, but there is significant variability in targeted sec-

93 DECISION TO AMEND THE FIRE FIGHTING CHEMICALS GROUP STANDARD 2017, Environmental Protection Authority (EPA), 21 December 2022.

94 List of New Pollutants under Key Control (2023 Edition) (Order No. 2022 of the Ministry of Ecology and Environment, the Ministry of Industry and Information Technology, the Ministry of Agriculture and Rural Affairs, the Ministry of Commerce, the General Administration of Customs, and the State Administration for Market Regulation promulgated on December 12, 29, effective from March 28, 2023)

95 See, <http://me.go.kr/home/web/board/read.do?pagerOffset=10&maxPageItems=10&maxIndexPages=10&searchKey=&searchValue=&menuId=286&orgCd=&boardId=1427590&boardMasterId=1&boardCategoryId=&decorator=> accessed 1 may 2023: See, <http://me.go.kr/home/file/readDownloadFile.do?fileId=210232&fileSeq=1> accessed 1 May 2023.

tors, scope, and approaches. For example, Maine has banned the intentional addition of PFAS to any product sold in the state, with time-limited derogations for the industry to adapt. New York has introduced prohibitions for intentional PFAS addition in food packaging and apparel. Conversely, multiple other states have not indicated intention to independently regulate PFAS or have signalled intention to default to federal regulations.

In other global regions, heightened regulatory development for control of PFAS is anticipated to align local approaches with existing regulations and emerging trends in Europe and USA.

Differences in existing and proposed global regulatory approaches are highlighted below and summarised according to market sector or industry. It is important to note that several regulatory proposals are actively in stakeholder consultation phase(s) and adjustments are expected following information retrieval, discussions, and more detailed evaluations and impact assessments.

1. Consumer Products

In the EU and under existing regulations, the use and concentration limits of PFAS in consumer products is based on the inclusion of specific PFAS in the varying regulations specified in the sections above. Time-limited exemptions have been facilitated for certain applications (e.g., for specialised professional textiles, Annex XVII derogations permit the use of C9-14 PFCAs above concentration limits until July 2023). The EU proposal takes a separate group-based approach and highlights that assessments have deemed that sufficiently strong evidence points to the existence of technically and economically feasible alternatives (Tables 9 and 10 of Annex XV Restriction Report) for most consumer products sectors like TULAC (textile, upholstery, leather, apparel, carpets), FCMs and packaging (cookware, food and feed packaging, etc.), cosmetic products (skin and hair care) and specialty products (ski wax). Thus, for these, no derogations are proposed. However, derogations are recommended for some specific uses. For example, a 12-year derogation is proposed for PPE since suitable alternatives have not yet been identified to date, and they are not likely to be available in the near future. This period also takes into account that when alternatives are identified, 12-36 months may be needed for product development, testing, supply chain approval and certification.

In the USA, most recent regulatory activity in this sector has been at state level. Many states are taking action to eliminate PFAS in various consumer products, including:[96]

- cosmetics (e.g., California, Colorado and Maryland);
- food packaging (e.g., California, Colorado, Connecticut, Hawaii, Maine, Maryland, Minnesota, New York, Rhode Island, Vermont and Washington); and
- textiles (e.g., California, Colorado, Maine, Maryland, New York, Vermont and Washington).

The USA States have mainly focused on restricting all PFAS contained in specific consumer products. For example, in addition to Proposition 65 inclusion, California enacted AB-1817 in September 2022, which will prohibit the manufacture, distribution, or sale of textiles containing intentionally added PFAS from 1 January 2025.[97] The legislation sets total organic fluorine (TOF) content limits for textile products of 100 ppm, effective from 1 January 2025, with reductions to 50 ppm effective from 1 January 2027.

In other countries, there are currently minimal legislative PFAS actions targeted specifically at consumer products. Denmark and Belgium, for example, have or are planning to prohibit certain PFAS-containing consumer products. Effective from May 2020, Denmark's Order No. 681 bans PFAS in food contact paper and board materials and articles.[98] Belgium is planning to prohibit the placing on the market of packaging containing PFAS from 1 January 2024.[99]

2. AFFF

Under EU REACH Annex XVII, PFAS is permitted for AFFF applications [firefighting foam for liquid fuel vapour suppression and liquid fuel fire (Class B

96 See, <https://www.saferstates.org/assets/Resources/PFAS-Momentum-Factsheet-2.8.2023.pdf> accessed 2 April 2023

97 California AB-1817 Product safety: textile articles: perfluoroalkyl and polyfluoroalkyl substances (PFAS).

98 Order No. 681 on materials in contact with food and penalties for the violation of related EU legislation.

99 Government of Belgium (July 7, 2022) "Pollution à Zwijndrecht – La Chambre veut l'interdiction des PFAS dans les emballages alimentaires." RTBF (in French).

fires) with the caveat that use will only be allowed on sites where all releases can be contained] until 2025. However, the EU PFAS Restriction Proposal for Firefighting Foams will restrict the formulation, sale, and use of all PFAS in firefighting foams following any derogation periods and is also likely to enter into force in 2025.

Similarly, New Zealand plans a complete ban on PFAS-containing firefighting foams after 3 December 2025.

At this time, the USA has no stated timeline for a complete AFFF ban. However, the DoD has stated that they will prohibit the use of fluorinated foams after 1 October 2024.[100] Because FAA and other industry groups reference DoD specifications, the majority of the private sector continues to use PFAS-based products for fire suppression although not all applications are strictly required to do so (depending on the situation). Some facilities have begun transitioning to F3 and water-based systems ahead of the new MILSPEC publication. PFAS-containing foams have not yet been banned at the federal level but are under increasing scrutiny at the state level. For example, the Washington state law limits the allowed uses of AFFF to FAA-certified airports, petroleum refineries and terminals, and certain chemical plants. Applications such as fire suppression in tunnels (as would be employed by the Department of Transportation) are not addressed by the exemption. Industrial facilities not classified under the exempted categories will not be able to purchase replacement products and will be required to replace their systems with F3 or water-based fire suppression.

3. Medical Devices

Under existing REACH regulations in the EU, the use of certain PFAS in medical devices is governed by the limits specifications and time-limited exemptions in the varying rules described in the sections above. For example, C9-14 PFCAs use above the concentration limits, as defined by Annex XVII for implantable medical devices (such as pacemakers), is permitted until July 2025 and for can coatings of metered-dose inhalers until August 2028. In the EU proposal, the derogations in this sector are again based on the type of medical devices, their invasiveness, and the identification and supply of alternatives. For implantable medical devices, hernia meshes, and tubes and catheters, there is evidence that technically feasible options do not exist and are likely to not be available at entry into force. Considering the essential health uses in this sector, a 12-year derogation period is proposed for most applications to allow sufficient time for research, development, and certification of alternatives, which is likely to take more than five years.

In the USA, there have been comparatively fewer federal regulatory actions targeting PFAS-containing medical devices. However, there are plans to legislate certain medical devices. For example, California[101] and Vermont[102] published draft Bills in January 2023 for menstrual products, which are classified under Federal Law as medical devices. These bills, if signed into law, will prohibit the manufacturing, distributing, selling, and offering for sale (in the respective state) of menstrual products containing intentionally added PFAS. The California and Vermont laws (if promulgated) will become effective on 1 January 2025 and 1 January 2026 respectively.

4. Specialised Industry Applications

Due to the unavailability of alternatives, many PFAS are deemed essential use for socioeconomic reasons, e.g., as crucial components of hydraulic fluids used in the aviation and aerospace industry, semiconductors, fluoropolymers used in petroleum and mining, and safety parts in the automobile industry.[103] To identify, develop, manufacture and certify alternatives, the EU proposal has recommended a 12-year derogation in these areas (Table 8 and 9 Annex XV report).

For some industrial applications, such as hard chrome plating, refrigeration, and mobile air-conditioning, evidence supports the feasibility for the development of economically viable and functionally suitable substitutions. Hence, a five-year derogation

100 National Defense Authorization Act for Fiscal Year 2020, S.1790 - 116th Congress (2019-2020)

101 California Assembly Bill AB 246 Product safety: menstrual products: perfluoroalkyl and polyfluoroalkyl substances. 17 January 2023

102 Vermont Senate Bill S 25 An act relating to regulating cosmetic and menstrual products containing certain chemicals and chemical classes and textiles and athletic turf fields containing perfluoroalkyl and polyfluoroalkyl substances 20 January 2023

103 Environ. Sci.: Processes Impacts, 2020,22, 2345-2373

is recommended in the EU proposal for the industry to adapt. Under existing EU regulations, time-limited exemptions are also in place for such applications. For example, the use of C9-14 PFCA is permitted at levels above those specified in Annex XVII for photolithography or etch processes in semiconductor manufacturing until July 2025. In other sectors such as construction (products such as architectural paints and coatings, architectural membranes, laminated window frames and polymer sealants) and electronics, alternatives are available or feasible and derogations have not been recommended in the EU restriction proposal.

The USA has proposed to restrict certain PFAS, such as PFOS and long-chain PFCAs, under federal law. Falling under the TSCA, the proposed Significant New Use Rules (SNURs) effectively ban a use, including for industrial applications, unless an exemption applies.[104] Manufacturers, importers, and processors of chemicals for any such use are required to submit a Significant New Use Notice (SNUN) to the EPA at least 90 days prior to carrying out a 'significant new use'. Contrary to the EU, the USA has a reporting and recordkeeping rule under TSCA Section 8(a)(7) that would require manufacturers (including importers) of a PFAS (if included under TSCA), in any year since 1 January 2011, to supply extensive information to the EPA for each year since the beginning of 2011. This rule, if promulgated, will apply to all industrial sectors.

At the USA state level, Maine has adopted a similar regulatory approach to the EU PFAS restriction proposal; products containing intentionally added PFAS cannot be sold (effective from 1 January 2030 for all new products containing PFAS).

5. Drinking Water

Because PFAS exposure pathways are generally limited to ingestion, drinking water regulations are a primary safeguard. A variety of regulatory limits have been promulgated internationally, reflecting a variety of assumptions in the underlying human exposure modelling. The majority of countries have employed an analyte-specific approach, regulating each PFAS chemical individually, while the EU has opted to regulate PFAS as a class, basing their standard on a total PFAS concentration. Regulatory limits (with few exceptions) are in the sub-part per billion range.[105] A detailed cost-benefit analysis of these regulations has not been attempted here.

6. Hazardous Substances

Classification of PFAS as a hazardous substance with disposal ramifications has not been a focus of regulatory action in the EU and UK. Rather, ECHA provides a database for waste disposal operators known as the Substances of Concern In articles as such or in complex objects (Products) (SCIP) established under the Waste Framework Directive (2008/98/EC).[106] The database supports and informs best management practices for handling PFAS-containing waste streams.

The USA EPA has announced proposed regulations to formally list PFOA and PFOS as hazardous substances with implications for release reporting, disposal restrictions, and remediation requirements. Only Alaska, Massachusetts, New Jersey, New York, and Vermont have promulgated regulations to include certain PFAS (depending on the state) as hazardous and subject to state programmes and restrictions accordingly.

VI. Conclusion

A range of different regulatory approaches have been and are being implemented across the globe, from focus on manufacture and production bans in the EU under REACH, to exposure limits and disposal practices in the USA. Even among the EU member nations and (in particular) across USA states, individual agencies have enacted a series of stand-alone policies ahead of broader union or federal mandates. Across all programmes, consideration of essential PFAS uses in multiple industrial sectors has led to requests for negotiation of future derogations considerate of the technical challenges associated with the

104 TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; 15 U.S.C. §2607(a)(7), 40 Code of Federal Regulations Part 705 Tentative, Docket EPA-HQ-OPPT-2020-0549

105 Values summarized on the ITRC website for convenience. See, <https://pfas-1.itrcweb.org/fact-sheets/> accessed 1 May 2023.

106 Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (Text with EEA relevance), 05 July 2018

identification of suitable replacement chemicals to maintain product functionality. However, given the global nature of our modern supply chain, regulatory actions such as the EU's PFAS restriction under REACH may impact multinational businesses based in other countries but doing business within the EU, inducing a ripple effect across the global economy. 3M's withdrawal as a PFAS manufacturer is perhaps telling of a broader shift in the marketplace. Future ramifications of these policies are the subject of much speculation, the full effects of which remain to be seen.

Appendix

Table 1: Concentration limits for non-polymeric and polymeric PFAS.

Non-polymeric PFAS	Polymeric PFAS
25 ppb[a] for any individual PFAS.[b] **250 ppb** for the sum of PFAS, optionally with prior degradation of precursors.*	**50 ppm** for PFAS with polymeric PFAS included.[c]

a ppb – parts per billion

b Polymeric PFAS excluded from quantification.

c If total fluorine exceeds 50 milligrams fluorine per kilogram (mg F/kg), the manufacturer, importer or downstream user may be requested to provide proof.

Table 2: Two proposed PFAS ROs.

Option 1	Option 2
Full PFAS ban with a limited number of (full) derogations. 18-month transitional period following enforcement of regulation.	Full PFAS ban with full and use-specific time-limited derogations.[a] 5- or 12-year derogation period. 18-month transitional period following enforcement of regulation.

a Manufacturers, importers and downstream users may have certain annual reporting obligations, including providing information on the substance identity, justification of use, conditions of use and safe disposal, and quantity placed on the market.

Developments in Fluoropolymer Manufacturing Technology to Remove Intentional Use of PFAS as Polymerization Aids

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Fluoropolymers are heavily impacted by the restriction proposal on per- and polyfluoroalkyl substances (PFAS) that has been recently published under the EU REACH Regulation.[1] *While matching the definition of PFAS due to their chemical composition and structure, fluoropolymers are significantly different from other substances in the PFAS family. The only substantial reason for concern associated to fluoropolymers is the use of non-polymeric PFAS as polymerization aids during the manufacturing process. In the past, environmental pollution caused by PFOA and PFOS, which are prominent non-polymer substances in the PFAS family, has attracted regulatory attention. PFOS has been restricted and PFOA has been banned under the EU Regulation on Persistent Organic Pollutants. This article highlights the progress that industry has made over the last years in relation to control of PFAS emissions due to their use in fluoropolymer production. Such a progress is based on the improvement of abatement techniques, but more importantly, on the removal of PFAS polymerization aids, introducing alternative technologies that do not require using such chemicals. It is expected that most of the fluoropolymer production will be developed completely free from PFAS polymerization aids in a relatively short time frame. Thus, it appears reasonable to claim that fluoropolymers that are manufactured without the use of PFAS polymerization aids should be exempted from any regulatory initiative, and that their uses should be allowed without any unjustified restriction.*

I. Introduction

The PFAS family of chemicals is currently under strong regulatory scrutiny globally. Some of the substances covered by this group are known for being highly harmful to the environment and human health, due to their persistency, bioaccumulation/mobility and other toxic effects. However, the broad definition that is frequently used to describe PFAS, which was not originally introduced to be used for regulatory purposes[2], results in a very large number of substances covered jointly in this family of chemicals, more than 4,700 according to the OECD[3] as being present on the global market. There have been significant efforts to group and classify the different substances that can be regarded as meeting the definition of PFAS (Figure 1). One such group is that of fluoropolymers.[4]

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1 ECHA, 'Registry of restriction intentions until outcome - Per- and polyfluoroalkyl substances (PFAS)' (2023).

2 J K Anderson, R W Brecher, I T Cousins, J DeWitt, H Fiedler, K Kannan, C R Kirman, J Lipscomb, B Priestly, R Schoeny, J Seed, M Verner, S M Hays, 'Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts' (2022) Regulatory Toxicology and Phamacology, 134.

3 OECD, 'Toward a new comprehensive global database of per- and polyfluoroalkyl substances (PFASs)' (2018) Series on Risk Management No. 39. Organisation for Economic Co-operation and Development.

4 Bruno Ameduri, 'Fluoropolymers: A special class of per- and polfluoroyalkyl substances (PFASs) essential for our daily life' (2023) Journal of Fluorine Chemistry 267, 110117.

One of the key features of fluoropolymers is that they fulfil the conditions set out by the OECD to meet the definition of Polymers of Low Concern (PLC). This has been demonstrated for the vast majority of these substances, accounting for >96% of global production.[5] This means that fluoropolymers are not toxic, mobile or bioaccumulative. While they are persistent, the lack of degradability during normal conditions of use and at end of life makes fluoropolymers completely inert and not hazardous to human health and the environment.

Due to their intrinsic nature based on the carbon-fluorine bond, fluoropolymers offer a combination of various properties of interest that render them highly valuable products in different industrial sectors such as renewable energy, in applications such as back sheets for photovoltaic panels and lubricants in wind turbines, binders and separators for lithium-ion batteries and proton exchange membranes and frame gaskets for hydrogen production and fuel cells. Fluoropolymers are also valuable in industries such as semiconductors, food and water processing, automotive, aerospace, chemical processing, electrical, electronics, and construction. It is to be noted that the broad applications of fluoropolymers, which are virtually irreplaceable in critical industrial sectors needed by modern society is not in scope of this paper, and significant information on this can be found in literature.[6]

II. Historical Concerns Related to Manufacture of Fluoropolymers

The manufacture of fluoropolymers has been flagged by researchers as a source of environmental damage in different locations in Europe (Italy, France, the Netherlands), the USA and China.[7] However, it needs to be stressed that this concern is not related to the fluoropolymers as individual substances, but to the use of non-polymeric PFAS that have been frequently used as polymerization aids. These Fluorinated Polymerization Aids (FPAs), also referred to as surfactants, facilitate the development and completion of the polymerization reaction. In the past, this use has led to specific situations of uncontrolled emissions of these surfactants, which are known to pose an environmental hazard.[8]

In terms of global production, fluoropolymers represent a very small share compared to the total amount of plastics, with estimated 320,000 tonnes of fluoropolymers in 2019[9] in front of 460 million tonnes of total plastics.[10] It is estimated that only 50% of fluoropolymer production requires the use of FPAs, based on standard manufacturing practices by industry to this date;[11] while manufacture of fluoropolymers via suspension process normally does not require the use of surfactants, these have traditionally been required to achieve high molecular weight polymer emulsions.[12]

5 Barbara J Henry, Joseph P Carlin, Jon A Hammerschmidt, Robert C Buck, L William Buxton, Heidelore Fiedler, Jennifer Seed and Oscar Hernandez, 'A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers' (2022) 14 Integrated Environmental Assessment and Management 13, 316–334; Stephen H. Korzeniowski, Robert C. Buck, Robin M. Newkold, Ahmed El kassmi, Evan Laganis, Yasuhiko Matsuoka, Bertrand Dinelli, Severine Beauchet, Frank Adamsky, Karl Weilandt, Vijay Kumar Soni, Deepak Kapoor, Priyanga Gunasekar, Marco Malvasi, Giulio Brinati, Stefana Musio, 'A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers' (2022) Integrated Environmental Assessment and Management.

6 Bruno Ameduri and Sergey Fomin, *Fascinating Fluoropolymers and Applications* (Elsevier, 2020); Bruno Ameduri, 'The Promising Future of Fluoropolymers' (2020) Macromol Chem Phys 221, 1900573; Bruno Ameduri, *Issues, Challenges, Regulations and Applications of Perfluoroalkyl Substances* (Oxford University Press, 2022).

7 Wouter A Gebbink, Laura van Asseldonk and Stefan P J van Leeuwen, 'Presence of Emerging Per- and Polyfluoroalkyl Substances (PFASs) in River and Drinking Water near a Fluorochemical Production Plant in the Netherlands' (2017) 51 Environ Sci Technol 19, 11057–11065; Rainer Lohmann, Ian T. Cousins, Jamie C. DeWitt, Juliane Glüge, Gretta Goldenman, Dorte Herzke, Andrew B. Lindstrom, Mark F. Miller, Carla A. Ng, Sharyle Patton, Martin Scheringer, Xenia Trier, and Zhanyun Wang, 'Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS?' (2022) Environ Sci Technol 54, 12820–12828; Xuan Jia, Hongyan Guan, Zhongbao Guo, Chengjing Qian, Yali Shi and Yaqi Cai, 'Occurrence of Legacy and Emerging Poly- and Perfluoroalkyl Substances in Fluorocarbon Paint and Their Implications for Emissions in China' (2021) 8 Environ Sci Technol Lett 11, 968-974.

8 Rob Bonta, Superior Court of the State of California, County of Alameda 10 November 2022.

9 ETC/WMGE Consortium Partners, 'Fluorinated polymers in a low carbon, circular and toxic-free economy - Technical report' <https://www.eionet.europa.eu/etcs/etc-wmge/products/etc-wmge-reports/fluorinated-polymers-in-a-low-carbon-circular-and-toxic-free-economy> accessed 1 May 2023.

10 OECD, 2022. Plastic pollution is growing relentlessly as waste management and recycling fall short, says OECD. Available at: https://www.oecd.org/environment/plastic-pollution-is-growing-relentlessly-as-waste-management-and-recycling-fall-short.htm. Last access December 2022.

11 Jaime Sales, Francisco Hernández, Deepak Kapoor, Marcel van den Noort, 'Fluoropolymers: The Safe Science That Society Needs' (2022) 5 International Chemical Regulatory and Law Review 1, 13-23.

12 Ebnesajjad, *Fluoroplastics, Volume 1: Non-Melt Processible Fluoropolymers - The Definitive User's Guide and Data Book* (Elsevier, 2014).

Aqueous emulsions are required to produce high performance grades of some fluoropolymers.[13] Surfactants are highly soluble in water, but the final fluoropolymer substances are not; hence after separation, the residual water contains amounts of dissolved surfactant, which may lead to PFAS emissions when FPAs are used.[14]

Another consequence of the use of these surfactants is that sometimes the final fluoropolymer product may carry residuals of such non-polymeric PFAS, which can be also emitted to the environment during the life cycle of fluoropolymers. Again, in this case there is an indirect pollution associated to fluoropolymers, not related to the intrinsic specific properties of these substances.

As a final step in the life cycle of fluoropolymers, disposal and waste treatment has been frequently flagged as a reason for concern of these products. However, recent studies have demonstrated that the waste generation of fluoropolymers is insignificant compared to that of other plastics,[15] and that the most common waste treatment technique for fluoropolymers - incineration - will not result in any PFAS species of concern.[16] In addition to this, fluoropolymers do not degrade during normal use or environmental conditions[17] and do not pose any significant risk if they are landfilled.[18]

In summary, it can be established that the only real source of concern for human health or the environment related to fluoropolymers is the use of PFAS as polymerization aids in the manufacture of these polymers of low concern. Providing efficient solutions that would completely neutralize such concerns would result in completely safe manufacture, use and disposal of fluoropolymers.

III. How to Avoid PFAS Emissions (Polymerization Aids) from the Fluoropolymer Value Chain?

For many years, industry has placed significant efforts to reduce emissions of PFAS from the manufacturing process of fluoropolymers. In order to achieve this goal, there are basically two options available:

1. To improve the abatement techniques and recovery of PFAS surfactants from the manufacture of fluoropolymers.
2. To develop alternative processes that do not require the use of such PFAS polymerization aids for the production of fluoropolymers.

In the case of item 1 above, significant improvements have occurred over the last years that have allowed for reduction of 99% of emissions of fluorinated surfactants since the 1990s.[19] More recent research brings that value as high as 99.99%.[20] Extensive literature exists in relation to control and treatment of emitted PFAS from industrial processes.[21] The strategies of containment involve the recovery, removal, purification, sorption techniques, microbial degradability and recyclability of the polymerization aids

13 Oleg N. Primachenko, Alexey S. Odinoko, Elena A. Marinenko, Yuri V. Kulvelis, Valerij G. Barabanov and Svetlana V. Kononova, 'Influence of sulfonyl fluoride monomers on the mechanism of emulsion copolymerization with the preparation of proton-conducting membrane precursors' (2021) Journal of Fluorine Chemistry 244, 109736.

14 Ebnesajjad, *Fluoroplastics, Volume 1: Non-Melt Processible Fluoropolymers - The Definitive User's Guide and Data Book* (Elsevier, 2014).

15 Conversio, 'Fluoropolymer waste in Europe 2020 – End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams' (2022).

16 Krasimir Aleksandrov, Hans-Joachim Gehrmann, Manuela Hauser, Hartmut Mätzing, Daniel Pigeon, Dieter Stapf and Manuela Wexler, 'Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas' (2019) 226 Chemosphere; RIVM, 'Per- and polyfluorinated substances in waste incinerator flue gases. Rijksinstituut voor Volksgezondheid en Milieu' (2021).

17 Danish EPA, 'Survey of PFOS, PFOA and other perfluoroalkyl and polyfluoroalkyl substances. The Danish Environment Protection Agency' (2013) LOUS Review, Environmental Project No. 1475, 2013.

18 Stephen H. Korzeniowski, Robert C. Buck, Robin M. Newkold, Ahmed El kassmi, Evan Laganis, Yasuhiko Matsuoka, Bertrand Dinelli, Severine Beauchet, Frank Adamsky, Karl Weilandt, Vijay Kumar Soni, Deepak Kapoor, Priyanga Gunasekar, Marco Malvasi, Giulio Brinati and Stefana Musio, 'A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers' (2022) Integrated Environmental Assessment and Management.

19 Daikin Chemicals, 'Measures concerning environment emission of PFAS' (2022) <https://www.daikinchemicals.com/company/sustainability/pfas.html> accessed 1 May 2023. Chemours, 'Our Commitment to Responsible Chemistry' <https://www.chemours.com/en/corporate-responsibility/sustainability-safety/our-commitment-to-pfas-stewardship> accessed 1 May 2023.

20 Rebecca DiStefano, Tony Feliciano, Richard A. Mimna, Adam M. Redding and John Matthis, 'Thermal destruction of PFAS during full-scale reactivation of PFAS-laden granular activated carbon' (2022) Remediation 32, 231–238.

21 ITRC, 'PFAS Technical and Regulatory Guidance Document and Fact Sheets: 12. Treatment Technologies' (2022) Interstate Technology and Regulatory Council; Jinxia Liu and Sandra Mejia Avendaño, 'Microbial degradation of polyfluoroalkyl chemicals in the environment: A review' (2013) Environment International 61, 98-114.

from off-gases, waste-water streams, aqueous dispersions, and final products. The recovery/recycling techniques of the polymerization aids depend on the final form of the fluoropolymer product: they can be removed when the aqueous emulsion is dried for sale as a solid (in the case of powder), or they can be thermally destroyed at high temperatures during the curing process (in the case of aqueous dispersion). Such techniques, including ion exchange technology for removal of FPAs from aqueous emulsions, have been applied for more than 20 years, and at present time, they are installed in most of the fluoropolymer manufacturing facilities around the world.

However, it needs to be acknowledged that achieving an absolute zero value of emissions in processes where PFAS are used is technically impossible. Frequently industry operates with the concepts of As Low As Reasonably Practicable/Achievable.[22] From that point, developing improved technologies becomes complex and significantly resource intensive for industry. Furthermore, with the development of ever more sophisticated analytical techniques, the possibility that (low) PFAS concentrations in the vicinity of industrial sites where these chemicals are used will be detected will continue to increase as well. This is certainly a positive development, due to the properties of the most dangerous PFAS as persistent, bio-accumulative, mobile and toxic. However, if the goal is to ensure zero emissions, it is highly unlikely that continued improvement of abatement techniques (which is nevertheless a clear necessity) will achieve this target.

Instead, option 2 appears to be the only realistic possibility to ensure that the emission of PFAS surfactants will be completely removed; if no PFAS surfactants are used in the manufacturing process of fluoropolymers, then no emissions will occur. Thus, the use of Non-Fluorinated Polymerization Aids (NFPA) can be considered as the most direct path forward to respond to the societal concern related to PFAS pollution associated to fluoropolymers.

However, it needs to be noted that both options are not mutually exclusive. The switch to fluoropolymer manufacture with the use of NFPA will also require the implementation of the most efficient abatement techniques, such as, use of ion exchange resin,[23] filtration[24] or foam fractionation.[25] This is because the process may still lead to small amounts of residual fluorinated by-products coming from side reactions between chemicals involved, such as monomers or the NFPA. Still, an adequate selection of surfactant and process conditions should allow for a minimisation of fluorinated residuals, particularly if compared to the situation where fluorinated surfactants are used.

Indeed, when comparing manufacturing processes of fluoropolymers that may use either FPAs or NFPAs, the whole life-cycle of all the chemicals involved in the process needs to be taken into account. The use of FPAs requires its manufacture, transport, storage and maintenance (e.g., cleaning) of the equipment used in those processes. All these activities will result in potential PFAS emission sources that have to be added to the possible emissions of the FPA (and residuals) that will be generated during the manufacture of the fluoropolymer. In the case of NFPA technology, only the contribution of residuals from the manufacture of fluoropolymer may contribute to emissions. Again, the fact that today such emissions can be adequately controlled via efficient abatement, e.g., by keeping values of fluorinated residuals well below the 250 ppb limit established in the restriction proposal[26] clearly results in favour of the transition to manufacturing processes of fluoropolymers involving NFPA technology.

An overview on the current situation about implementation of NFPA technology and expected future developments is provided next.

1. State of the Art Related to NFPA Technology for the Manufacture of Fluoropolymers and Path Forward

Over the past years, the fluoropolymer industry has undertaken significant efforts in continued attempts

22 HSE, 'ALARP at a glance. Health and Safety Executive' (2022) <https://www.hse.gov.uk/managing/theory/alarpglance.htm> accessed 1 May 2023.

23 Fuhar Dixit, Rahul Dutta, Benoit Barbeau, Pierre Berube and Madjid Mohseni, 'PFAS removal by ion exchange resins: A review' (2021) Chemosphere, 129777.

24 EPA, 'Reducing PFAS in drinking water with treatment technologies' <https://www.epa.gov/sciencematters/reducing-pfas-drinking-water-treatment-technologies> accessed 1 May 2023.

25 Sanne J. Smith, Karin Wiberg, Philip McCleaf and Lutz Ahrens, 'Pilot-Scale Continuous Foam Fractionation for the Removal of Per- and Polyfluoroalkyl Substances (PFAS) from Landfill Leachate' (2022) ACS EST Water 5, 841–851.

26 ECHA, 'Registry of restriction intentions until outcome - Per- and polyfluoroalkyl substances (PFAS)' (2023) <https://echa.europa.eu/es/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b> accessed 1 May 2023.

to introduce NFPA technologies in the manufacture of fluoropolymers. An overview on patents that have been filed on technology based on non-fluorinated surfactants demonstrates that this is an effort that the whole industry has taken in parallel, and not limited to the initiative of one or a reduced group of suppliers. Several manufacturers of fluoropolymers have filed multiple patents on NFPA technology over the past 2 decades. This explains a high focus and investment in this direction by the industry. Table 1 (Appendix) provides a list of identified patents related to the use of NFPA technologies for the manufacture of fluoropolymers as published over the last years. While this is not an exhaustive list of initiatives in this field, it provides a good description of efforts developed by the whole fluoropolymer industry.

It should be noted that, even if Table 1 lists patents filed in the XXI Century, initiatives to introduce NFPA technology in the manufacture of fluoropolymers have been on-going since the 1960s.[27]

2. Commercialization of NFPA Technology and Successful Market Acceptance

As of today, it is assumed that there are technologies available that allow for the manufacture of more than 80% of fluoropolymer global production in volume without the use of FPAs.[28] This includes 100% of the three main fluoropolymers by volume: polytetrafluoroethylene (PTFE), polyvinylidene fluoride (PVDF) and fluoroelastomers (FKM). While progress on PVDF was achieved around 15 years ago[29], and some grades of PTFE and FKM have been traditionally manufactured without the use of FPAs, success with other PTFE grades (aqueous dispersions and fine powders) and other FKM grades has only been possible in the last months. Progress on smaller volume products such as is poly (TFE-co-perfluoroalkoxyvinylether) copolymers or perfluoro(alkoxyvinylether)s (PFA) have also been recently announced, and it is expected that further developments will be confirmed in the next months that will involve other fluoropolymers.

It needs to be noted that, while such technologies are currently available, it is not expected that all the suppliers will be in a position to integrate them in their manufacturing processes at the same time. This means, for example, that while one supplier may have developed a procedure to manufacture all grades of PTFE without the use of FPAs, this may not yet be feasible today for all the suppliers. While sublicensing of rights to a specific technology is possible, full implementation of these procedures by all the suppliers may take some time.

For many years, the fluoropolymer industry has made efforts to develop alternative technologies that do not require the use of FPAs. However, it is in the recent past when different fluoropolymer manufacturers have increased the announcements of different developments to replace technologies based on FPAs, either by introducing NFPAs, or by turning to completely alternative processes that simply remove the use of surfactants.[30]

In order to be considered as a completely viable option for fluoropolymer manufacture, the alternative processes must lead to the production of grades that are accepted by downstream users in terms of quality and performance. This can be confirmed since thousands of metric tonnes of fluoropolymers manufactured without the use of FPAs have already been introduced on the global market and have been well accepted by customers. In recent years, it was only possible to manufacture those fluoropolymers with FPAs, however this situation has changed following recent developments by industry. Furthermore, these grades have to ensure that any water-soluble fluorinated by-products present in the final product are brought to insignificant levels, which can

27 Hoashi Juzaemon, Stabilized, concentrated polytetrafluoroethylene dispersions containing non-ionic surfactants. U.S. Patent No. 3,301,807. 31 Jan. 1967.

28 Jaime Sales, Francisco Hernández, Deepak Kapoor, Marcel van den Noort, 'Fluoropolymers: The Safe Science That Society Needs' (2022) 5 International Chemical Regulatory and Law Review 1, 13-23.

29 PCI, 'Arkema Eliminates Fluorosurfactants from Kynar 500® PVDF' (2008) <https://www.pcimag.com/articles/88876-arkema-eliminates-fluorosurfactants-from-kynar-500-pvdf> accessed 1 May 2028.

30 Chemours, 'Chemours Announces Process Innovation with New Viton™ Fluoroelastomers Advanced Polymer Architecture (APA) Offering' (2022) <https://www.chemours.com/en/news-media-center/all-news/press-releases/2022/chemours-announces-process-innovation-with-new-viton-fluoroelastomers-advanced-polymer-architecture> accessed 1 May 2022: Solvay, 'Producing new fluoropolymers without fluorosurfactants' (2022) <https://www.solvay.com/en/article/eliminating-pfas> accessed 1 May 2023; Gujarat Fluorochemicals, 'Company Announcements' (9 March, 2022) <https://www.gfl.co.in/upload/pages/ebce5fed9030753d0ee651bf1f48d0a0.pdf> accessed 1 May 2023; Gujarat Fluorochemicals Limited, 'Company Annoucement' (27 August, 2022) <https://www.gfl.co.in/assets/pdf/Announcement-on-NFPA-technology-FKM-27-Aug-2022.pdf> accessed 1 May 2023; Gujarat Fluorochemicals Limited, 'Company Annoucement' (30 November, 2022) <https://gfl.co.in/assets/pdf/GFL%20Announcement%2030.11.22_new.pdf> accessed 1 May 2023.

also be guaranteed by some suppliers using known analytical methods.

In the recent past, and mainly in 2022, various fluoropolymer manufacturers have released statements announcing discontinuation of use of FPAs in the manufacturing of specific fluoropolymers. A summary of latest announcements is given in Table 2 (Appendix).

The fluoropolymer user industry has already witnessed the transition when PFOA was substituted by other PFAS polymerization aids, except in China where PFOA is still in use.[31] They have now become sensitive to the potentially negative aspects of FPAs currently in use replacing PFOA.[32] Hence, the user industry is requesting fluoropolymer manufacturers to switch to NFPAs. There is an urgency to qualify new versions of fluoropolymer products produced without the use of fluorinated polymerization aids. The regulatory developments from various authorities are pushing the industry to swiftly move towards sustainable technologies. As a result, fluoropolymers produced with NFPA technology are a commercial success and that further motivates the industry to work harder in this direction.

IV. A Regulatory Proposal for Fluoropolymers

The EU Chemicals Strategy for Sustainability (CSS) towards a Toxic-Free Environment proposes the development of a horizontal essential use concept to apply across chemicals legislation (European Commission, 2020). The CSS commits to “define criteria for essential uses 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”.

Most harmful substances as defined in the CSS are chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative. It also covers chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to specific organs. It is clear that fluoropolymers as independent substances do not fall into the category of Most Harmful Chemicals as defined in the CSS, based on[33]:

- Fluoropolymers are Polymers of Low Concern as per well-established OECD criteria
- Fluoropolymers are insoluble, non-mobile, non-bio accumulative and non- toxic

However, the FPAs that have been traditionally used in the manufacture of fluoropolymers are small non-polymeric PFAS substances of low molecular weight such as perfluorooctanoic acid (PFOA), ammonium salt of hexafluoropropylene oxide dimer acid (HFPO-DA, or GenX), ammonium 4,8-dioxa-3H-perfluorononanoate (ADONA), or perfluorohexanesulfonic acid (PFHxS) might fall into the category of Most Harmful Chemicals and they would therefore require regulatory control. It is important to highlight that, as mentioned above, at present between 50 and 80% of fluoropolymers do not require the use of fluorinated polymerization aids (depending on suppliers and implemented technology).

Any regulatory process on fluoropolymers should start by differentiating if the polymer has been manufactured with the use of FPAs. If this is not the case, then the fluoropolymer substance should be excluded from any legislative action, because there is no justification to regulate a chemical that will not pose any concern to human health or the environment.

If FPAs have been used in the manufacturing process, fluoropolymers should only be used in situations where the use can be considered to be essential. While the concept of essential use is still under development[34], this is expected to include situations in which it can be clearly demonstrated that the application is critical to ensure health, safety, and an adequate functioning of society. It is out of the scope of this article to discuss about the conditions under which essential use could be demonstrated. Yet it is

31 Rainer Lohmann, Ian T. Cousins, Jamie C. DeWitt, Juliane Glüge, Gretta Goldenman, Dorte Herzke, Andrew B. Lindstrom, Mark F. Miller, Carla A. Ng, Sharyle Patton, Martin Scheringer, Xenia Trier, and Zhanyun Wang, 'Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS?' (2022) Environ Sci Technol 54, 12820–12828.

32 Bruno Ameduri, *Issues, Challenges, Regulations and Applications of Perfluoroalkyl Substances* (Oxford University Press, 2022).

33 (n 5).

34 Cefic, 2022. Regulating Chemicals Based on the Essential Use Concept. Available at: https://cefic.org/policy-matters/defining-europes-essential-chemical-for-society/. Last access November 2022; Wood 2022, prepared for European Commission, DG Environment. Supporting the Commission in developing an essential use concept. Workshop report. Available at: https://environment.ec.europa.eu/system/files/2022-05/Essential%20Use%20Workshop%20Report%20final.pdf . Last access December 2022.

expected that many applications of fluoropolymers would meet these criteria.[35]

The essential use concept will be linked to the availability of alternatives. In cases where viable alternatives are proven to be available for a specific use of fluoropolymers, the use should be restricted so that it can be covered by the alternatives. Again, detailed discussions will be required to demonstrate viability of alternatives, particularly in situations where health and safety parameters (or even adequate functioning of society, depending on the case) will be critical. In such cases, equivalent performance to that provided by fluoropolymers will be necessary since downgrades in performance could have extremely negative impacts for the environment or the population. Likewise, the typical parameters of overall reduced risk and economic availability of the alternative (and in sufficient amount) will have to be carefully evaluated. So, availability of alternatives would have to be evaluated with a broad perspective covering items such as performance, accessibility, resource efficiency, waste generation, cost, availability, stability and lifetime. Where viable alternatives are not found for essential uses of fluoropolymers manufactured with FPAs, derogations from the impact of upcoming regulatory restrictions should be granted. Such derogations would need to be based on the introduction of all existing abatement techniques based on the most modern developments, plus the guarantee of a maximum PFAS content in the final product. For example, 250 ppb as has been included in the restriction proposal.[36] However, such derogations should be time limited to provide incentives to move suppliers to fully implement manufacturing process involving NFPA technology as soon as possible.

Figure 2 displays a schematic overview of the proposed regulatory path for fluoropolymers. In the absence of a definitive definition of “Essential Use Concept”, the term 'Critical Use for Society' is used.

V. Conclusions

The manufacture of certain grades of fluoropolymers had traditionally required the use of FPAs (short-chain PFAS) to ensure an optimal production. This practice has resulted in PFAS emissions and pollution of certain areas around manufacturing and processing sites, which has been a reason of major concern for the society. This has also triggered significant regulatory actions globally against PFAS. Fluoropolymers have been impacted by such actions, due to use of non-polymeric PFAS in the manufacturing process and the fact that they meet the very broad definition of PFAS based on structure.

For many years the fluoropolymer industry has been looking for alternative technologies that would help to remove the use of FPAs while ensuring top quality end-products. For this to be assured, not only commercial acceptance is required, but it also needs to be ensured that the final fluoropolymer will not lead to emissions of undesirable PFAS. The fact that industry has placed substantial efforts in such developments is proven by the relatively large number of patents that have been deposited over the last two decades.

Due to the increased regulatory pressure, and also to a better understanding by industry of the increasing constraints in terms of societal acceptance of chemical risk, significant progress has been achieved over the past years on the development of NFPA technology. In fact, only in the year 2022, up to 5 announcements from 3 different fluoropolymer suppliers have been released describing upcoming implementation of different manufacturing methods that will remove the need to continue using FPAs. Such announcements are not only based on achieved technical progress, but also on successful introduction of new fluoropolymer grades on the market, including customer acceptance. This demonstrates that such NFPA technology is not a vague concept or an aspiration, but a reality that should be developed by industry in a relatively short timeframe.

It is possible that not all suppliers will be ready to introduce such changes at the same pace, for every single fluoropolymer grade. Due to the well-established high value of fluoropolymers to many critical applications for society, it is expected that those uses should be allowed to continue, while likely on a time-limited basis. Nevertheless, efforts should be made by industry to ensure that all feasible abatement techniques are in place to guarantee that PFAS emissions from the manufacture of fluoropolymer is kept as low as possible.

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35 Bruno Ameduri, 'The Promising Future of Fluoropolymers' (2020) Macromol Chem Phys, 1900573.

36 ECHA, 'Registry of restriction intentions until outcome - Per- and polyfluoroalkyl substances (PFAS)' (2023).

This article also suggests a regulatory frame for fluoropolymers which is based on the need to exclude fluoropolymers that are manufactured with NFPA technology from any future restriction on their use. This is based on the fact that fluoropolymers are substances that pose no hazard to human health or the environment. Removing FPAs from their manufacture takes away the only real concern associated to fluoropolymers. The lack of degradability and the possibility to effectively destroy them during end-of-life without generating further PFAS emissions supports this principle. The proposal considers the need of other considerations such as uses that are critical for society (pending a final definition of the essential use concept) or the availability of alternatives to provide derogations to continue using fluoropolymers manufactured with FPAs, which should in any case be granted under specific time limits and with the obligation to introduce highly efficient abatement techniques to minimize emissions.

Appendix

Table 1: Summary of identified patents on fluoropolymers and NFPA (in no particular order)

Name of the patent	Company	Application	Reference
Fluoropolymer dispersions containing no or little low molecular weight fluorinated surfactant	3M	United States	Dadalas et al., 2005
Polymerization of Halogen-Containing Monomers Using Siloxane Surfactant and Aqueous Composition	ARKEMA	United States	Wille et al., 2005a
Polymerization of fluoromonomers using 3-ally-loxy-2hydroxy-1propanesulfonic acid salt as surfactant	ARKEMA	United States	Wille et al., 2005b
Emulsifier free aqueous emulsion polymerization to produce copolymers of a fluorinated olefin and hydrocarbon olefin	3M	United States	Kaspar et al., 2006
Process for preparing fluoropolymer dispersions	SOLVAY SPECIALTY POLYMERS ITALY	United States	Kapeliouchko et al., 2007
Process for preparing fluoropolymer	DAIKIN	United States	Otsuka et al., 2009
Preparation and Stabilization of Fluoropolymer Dispersions by Aqueous Emulsion Polymerization with Carbosilane Surfactants	3M	United States	Bissinger et al., 2010
Aqueous process for making fluoropolymers	ARKEMA	United States	Amin-Sanayei et al., 2011
Polymerization of Fluoropolymers Using Alkyl Phosphonate Surfactants	ARKEMA	United States	Durali et al., 2012
Aqueous Process for Making a Stable Fluoropolymer Dispersion	ARKEMA	United States	Amin-Sanayei et al., 2012a
Aqueous Process for Making Polyvinylidene Fluoride Dispersion	ARKEMA	United States	Amin-Sanayei et al., 2012b
Polymerization of fluoropolymers using polycaprolactone	ARKEMA	European patent specification	Hedhi, 2013
Polymerization of fluoropolymers using non-fluorinated surfactants	ARKEMA	United States	Durali et al., 2014
Synthesis of making 2,3,3,3-tetrafluoropropene containing fluoropolymers	ARKEMA	United States	Amin-Sanayei et al., 2014
Method for producing aqueous fluorinated polymer dispersion, aqueous fluorinated polymer dispersion and fluorinated polymer	AGC	United States	Toyoda et al., 2015

Fluoropolymer Compositions Containing a Polyol Compound as Emulsifier and Methods of Making Them	3M	United States	Zipplies et al., 2015
Method of producing fluoropolymers using alkyl sulfate surfactants	ARKEMA	United States	Amin-Sanayei et al., 2016
Method of Producing Fluoropolymers Using Acid-Functionalized Monomers	ARKEMA	United States	Durali et al., 2016
Aqueous polymerization of fluoromonomer using hydrocarbon surfactant	CHEMOURS	European patent specification	Brothers et al., 2016
Employing polyalkylene oxides for nucleation in aqueous polymerization of fluoromonomer	CHEMOURS	United States	Brothers et al., 2019
Fluoropolymer aqueous dispersion production method and fluoropolymer aqueous dispersion	DAIKIN	United States	Hayashi et al., 2020
Method for stabilizing aqueous dispersions of fluorinated polymers	SOLVAY SPECIALTY POLYMERS ITALY	United States	Carella et al., 2020
Peroxide curable fluoropolymers obtainable by polymerization with non-fluorinated emulsifiers	3M	United States	Jochum et al., 2020
Method for producing modified polytetrafluoroethylene, method for producing modified polytetrafluoroethylene powder, and method for producing stretched porous material	AGC	United States	Higuchi et al., 2020
Process for preparing fluoropolymers and fluoroelastomers in presence of a non fluorinated sulfonate type hydrocarbon containing surfactant thereof	GUJARAT FLUOROCHEMICALS	European patent specification	Chauhan et al., 2022

Table 2. Summary of recent announcements by fluoropolymer manufacturers on commercial progress to introduce NFPA technology in the manufacture of fluoropolymers that previously required the use of FPA.

Development of NFPA technology by fluoropolymer manufacturers	
PTFE Aqueous dispersions	Gujarat Fluorochemicals (2022a)
PTFE Fine powders	Gujarat Fluorochemicals (2022c)
PVDF	Arkema (PCI, 2008), Solvay (2022), Gujarat Fluorochemicals (2022c)
FKM	Chemours (2022b), Solvay (2022), Gujarat Fluorochemicals (2022b)
PFA	Gujarat Fluorochemicals (2022c)

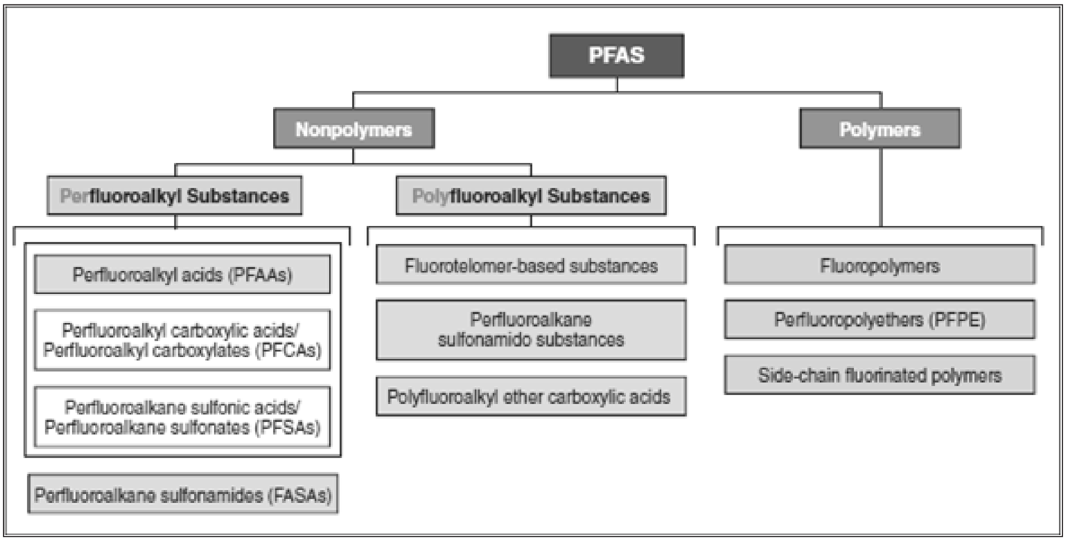

Figure 1: Commonly recognized PFAS groups of substances

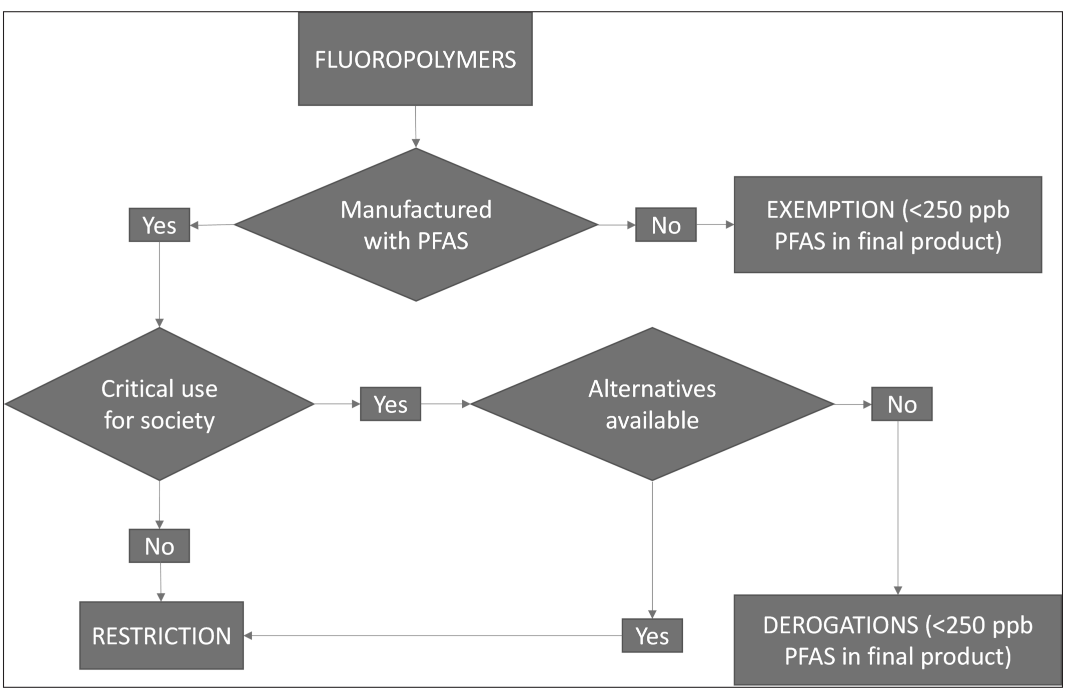

Figure 2: Summary of the regulatory process recommended for fluoropolymers

Critical Use of Fluoropolymers in the Functioning of Modern Society

*Jaime Sales, Michael Schlipf and Deepak Kapoor**

In the context of the upcoming restriction of PFAS, there appears to be significant confusion concerning the most relevant sectors where fluoropolymers are used. This paper intends to clarify that fluoropolymers are used mainly in industrial sectors of high value to society. The outstanding combination of properties that fluoropolymers exhibit makes them extremely valuable materials in a wide variety of applications. While there have been some historic uses in consumer applications, these uses are currently anecdotic, particularly for those linked to very dispersive uses (which excludes use in cookware), and represent a minute proportion of the overall uses when compared to industrial applications, where fluoropolymers' outstanding properties are capitalized on. Fluoropolymers contribute decisively to the progress and well-being of society in five key areas: safety & well-being, environment and circularity, decarbonization, performance and comfort, being the latter the only one that can be attributed to dispersive consumer applications.

I. Introduction

For many years, Per- and polyfluoroalkyl substances (PFAS) have been at the centre of the regulatory debate in many jurisdictions. In Europe, this became even more intense in 2020, after 5 Member States of the European Economic Area expressed an intention to file a restriction proposal under the REACH Regulation on all PFAS.[1] Since then, different debates have taken place involving various stakeholders, trying to clarify which specific chemicals would be impacted by the restriction, and to which extent. The definition[2] used by regulators to define the scope of the proposal leads to approximately 10,000 chemicals potentially under the umbrella of this initiative. The fact that PFAS can be categorised in a significant variety of different sub-groups or sub-families requires certain technical knowledge to fully understand such differences and what is more, the different areas of applications of the components of those sub-groups, which can involve completely opposite fields of application.

Fluoropolymers are a differentiated sub-group in the PFAS universe, pertaining to the group of polymeric PFAS. Even in this group, they can be clearly separated from other polymers due to their composition and structures.[3] These differences apply also to the sectors in which the different materials covered by the PFAS definition can be used. For example, while fluoropolymers are used mainly in industrial applications, other fluorinated polymers (e.g., the so-called Side Chain Fluorinated Polymers) see extensive use in dispersive consumer applications, such as textiles, upholstery, leather, apparel and carpets (TULAC).

Due to their highly valuable properties (e.g., non-stick, temperature resistant, and durability) fluoropolymers have also seen some use in applications with potential consumer contact. The most classical

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1 ECHA, 'Five European states call for evidence on broad PFAS restriction' (2020) ECHA/NR/20/13 <https://echa.europa.eu/-/five-european-states-call-for-evidence-on-broad-pfas-restriction> accesed 1 May 2023.

2 OECD, Toward a new comprehensive global database of per- and polyfluoroalkyl substances (PFASs)' (2020) Series on Risk Management No. 39. Organisation for Economic Co-operation and Development.

3 Jaime Sales, Francisco Hernández, Deepak Kapoor, Marcel van den Noort, 'Fluoropolymers: The Safe Science That Society Needs' (2022) 5 International Chemical Regulatory and Law Review 1, 13-23.

one is the use for coating frying pans to grant anti-adherence properties, or in professional or technical clothing.[4] Direct consumer uses of fluoropolymers are possible, such as in cosmetics,[5] ski waxes [6] or as lubricant for chains in bicycles.[7] However, taking into consideration all the possible applications in which fluoropolymers are used, the contribution of dispersive consumer uses is minimal. Nonetheless, it appears that the relevance of those consumer uses in the regulatory discussion has been disproportionately magnified in comparison with the more critical industrial uses, which are frequently ignored or hidden by certain stakeholders.

Under REACH the correct reporting of the uses of a substance is essential to properly assess the risks associated with its use. Besides manufacture and formulation, the so-called 'end uses' need to be reported. According to ECHA Guidance,[8] 'end-use' means the use of a substance as such or in a mixture, as a last step before the end-of-life of the substance, namely before the substance is consumed in a process by reaction during use (including intermediate use), is emitted to waste streams or the environment or is included into an article. The corresponding definitions of the different end-uses following ECHA Guidance are as follows:

- **Use at industrial site**: All end-uses of the substance (as such or in a mixture) carried out at industrial sites should be reported under this life cycle stage.
- **Widespread use by professional workers**: Widespread uses by professional workers correspond to uses carried out in the context of commercial activities and assumed to take place in most towns of a certain size, by multiple actors each at low scale e.g., local garage, small cleaning businesses.
- **Consumer use:** All end-uses of the substance as such or in a mixture carried out by consumers can be reported under the consumer use life cycle stage.

However, if the substance becomes part of an article, the subsequent life cycle stage (the service life) is to be considered additionally, as follows:

- **Service life**: For a given substance incorporated into an article, the service life is considered to be the period of time an article remains in service (or in use). Articles containing the substance can be used or processed by consumers, by workers at industrial sites and/or by professional workers.

Based on these definitions, the use of frying pans coated with fluoropolymers is not a consumer use; instead, the use of those pans has to be evaluated as a service life. In contrary to the use of a frying pan coated with fluoropolymers uses like cosmetics, ski waxes or bicycle chain lubricants are direct consumer end-uses.

II. Reasons Why Fluoropolymers are Used and Benefits They Provide

The properties that fluoropolymers provide are well known and have been discussed previously by different authors[9] and can be summarised as follows:

- Inertness and non-reactivity; high resistance to corrosion and chemical attack.
- Low and high temperature resistance: with a range as large as -263°C to +260°C for Polytetrafluoroethylene (PTFE).
- Very low coefficient of friction to any solid.
- Low and ultra-low permeation rates.
- Ultraviolet radiation (UV) resistance.
- Excellent electrical insulation, low dielectric constant, low variations of conductivity.
- High level of fire safety; no flame propagation and low smoke generation.

4 Performance Fluoropolymer Partnership, 'Consumer Products' (2023) <https://fluoropolymerpartnership.com/fluoropolymer-applications-and-uses/consumer-products/> accessed 1 May 2023.

5 US FDA, 'Per and Polyfluoroalkyl Substances (PFAS) in Cosmetics' (2022) <https://www.fda.gov/cosmetics/cosmetic-ingredients/and-polyfluoroalkyl-substances-pfas-cosmetics> accessed 1 May 2023.

6 Wood Group, 'Update of market data for the socio-economic analysis (SEA) of the European fluoropolymer industry' (2022) <https://fluoropolymers.plasticseurope.org/application/files/1216/5485/3500/Fluoropolymers_Market_Data_Update_-_Final_report_-_May_2022.pdf> accessed 1 May 2023.

7 Juliane Glüge, Rachel London, Ian T. Cousins, Jamie DeWitt, Gretta Goldenman, Dorte Herzke, Rainer Lohmann, Mark Miller, Carla A. Ng, Sharyle Patton, Xenia Trier, Zhanyun Wang, and Martin Scheringer, 'Information Requirements under the Essential-Use Concept: PFAS Case Studies' (2022) 56 Environ Sci Technol 10, 6232–6242.

8 ECHA, 'Guidance on Information Requirements and Chemical Safety Assessment' (2015) 12.

9 Barbara J Henry, Joseph P Carlin, Jon A Hammerschmidt, Robert C Buck, L William Buxton, Heidelore Fiedler, Jennifer Seed and Oscar Hernandez, 'A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers' (2022) 14 Integrated Environmental Assessment and Management 13, 316–334; Chemservice, 'Analysis of alternatives to fluoropolymers and potential impacts related to substitution in different sectors of use' (2022).

- High and ultra-high purity with extremely low leach out properties.
- Stress-crack and cut-through resistance.
- Flex fatigue properties enabling thermal expansion/contraction in temperature cycles.
- Biocompatibility.
- High Flex life.
- Durability.
- Hydrophobicity; neither water nor water-containing substances wet fluoropolymers, providing excellent repellent properties to many chemicals.
- Non-stick, and consequently non-fouling properties, along with sufficient bonding in certain multilayer applications.

The benefits that the use of fluoropolymers bring to the different applications in which they are used, based on the combination of the properties described above, can be categorised in mainly 5 groups.

1. Safety

Fluoropolymers are materials known for their outstanding chemical resistance. They can resist attack from virtually any chemical, particularly strong acids, bases and other corrosive substances. In parallel, they are also resistant to high and low temperatures, allowing high reliability in a broad temperature range. This grants fluoropolymers their extreme durability. Due to this combination of properties, fluoropolymers are essential materials in, for example:

- **Chemical processing industry**: whenever harsh chemicals or stringent conditions of use are required (e.g., high temperature operations), fluoropolymers are the material of choice. They ensure reliability of systems which, in case of failure, could result in high-risk situations for workers or the environment, due to potential leakage, spills or releases of highly corrosive substances at very high temperature.
- **Aerospace industry**: fluoropolymers are used for insulation of electrical and data transmission cables. These cables can be subject to extreme conditions where ensuring reliability is critical. As an example, it is estimated that around 300 km cables are needed in regular commercial airplanes, reaching close to 500 km in some of the most modern planes. These cables need to perform in variable conditions, such as high temperatures near the engine and low temperatures in areas close to the external part of the fuselage at high altitudes. On top of this, exposure to aggressive oils is to be expected for these cables. Any malfunction of the electrical system will lead to high-risk situations for passengers and crew. Fluoropolymers provide the best performance, particularly due to their excellent dielectric properties that prevent electric arc fires in cables. As an example, the case of the Swissair 111 flight that crashed near Peggy's Cove, Nova Scotia, on the night of 2 September 1998, resulting in the death of 215 passengers and 14 crew members can be highlighted. The conclusion from the accident investigation report[10] concluded that the accident was caused by a fire generated by electric arc effect, most likely via electrical cable associated with the in-flight entertainment network. It was determined that aircraft certification standards for material flammability were inadequate. It is also worth mentioning that fuel systems in aircrafts are based on fluoropolymer lined equipment, as they are stable in a kerosene environment.

The high chemical resistance of fluoropolymers, combined with smooth surfaces and extremely low amount of leachables, brings about enhanced durability and prevents degradation potential during use. This allows these materials to guarantee high purity of process streams that are handled with the aid of fluoropolymer-based products (e.g., pipes, tubes, pumps, valves, joints, gaskets, seals, o-rings). As previously discussed, this is relevant for the chemical processing industry. But high purity is also critical to ensure safety conditions in other areas, for example:

- **Pharmaceuticals**: the production of medicines and vaccines require highly pure streams avoiding contamination that may come from process equipment, due to degradation from wear or to the effect of aggressive chemicals. Failure to grant this property could result in undesired health effects for the general public via contamination. Furthermore, the fact that articles based on fluoropolymers can be cleaned at high temperatures provides an advantage in front of other materials

10 TSBC, 'Transportation Safety Board of Canada. Swissair 111 Investigation Report - Executive Summary' (2003) <https://www.tsb.gc.ca/eng/medias-media/fiches-facts/a98h0003/sum_a98h0003.html> accessed 1 May 2023.

that may be used in the pharma sector such as glass, which has a tendency to break.

- **Food processing**: a wide variety of food processes must be handled via complex equipment. From conveyor belts to tubes transferring liquids (e.g., coffee machines), fluoropolymer-based equipment guarantees high purity of food avoiding contamination with impurities that could otherwise reach humans. Here, fluoropolymers' outstanding non-stick properties due to their very low coefficient of friction play a key role.
- **Water filtration**: fluoropolymers are necessary elements in membranes used in water filtration systems. The use of lower performing products could reduce the ability of those membranes to ensure clean water that may later be consumed by the general population. Water systems are frequently cleaned with chlorine under pressure. While most materials tend to hold on to bacteria and algae, this is not the case of fluoropolymers.
- **Medical implants**: perhaps the most evident proof that fluoropolymers are intrinsically safe is that they are the material of choice for a variety of medical implants, including cardiovascular stents, patches and other products that are introduced in the human body and intended to remain there for a long time. It therefore becomes evident that fluoropolymers play a vital role in safety of humans.

2. Decarbonization

Fluoropolymers are critical materials that enable the EU Green Deal. Without these materials, key technologies that are expected to help Europe to achieve its ambitious energy transition will not be available, or their efficiency will be seriously compromised. Some examples are the following:

- **Lithium-ion batteries**: fluoropolymers are used as electrode binders and separator coatings in these batteries, providing interconnectivity within each electrode. This facilitates electronic and ionic conductivity, increasing the cell manufacturing productivity and the cell safety. Fluoropolymers offer unparalleled cohesive and adhesive properties under high voltage, allowing for closely packed cathode active materials for high density electrodes. With the use of fluoropolymers, different battery components can be packed more closely together, improving the energy efficiency of a single unit, and helping reduce overall size.
- **Proton exchange membranes in green hydrogen**: electrolysers and fuel cell membranes are used in the production of green hydrogen by an electro-chemical reaction. To enable the movement of protons from the anode to the cathode side of the fuel cell, a proton exchange membrane made of fluoropolymers is used due to the efficiency and unique durability, chemical and temperature resistance properties that fluoropolymers offer for this application.
- **Renewable energies**: fluoropolymers improve the efficiency and durability of photovoltaic panels used in solar energy, as well as for wind turbines.
- **Lambda sensors in automotive**: fluoropolymers are used in lambda sensor cables due to their resistance to high temperatures and chemicals, dielectric strength, flexibility, and electrical insulator properties. In vehicles, lambda sensors adjust the fuel amount that is sent to the engine cylinders by optimizing the air and fuel mixture, which in turn will make the engine work properly and reduce carbon monoxide emissions. Lambda sensors allow for this control system via measurement of oxygen in exhaust fumes. This is a critical element in cars and vehicles to control the rate of gas emissions by ensuring that the catalytic converter works in an efficient way. Lambda sensors ensure that the car complies with the European regulations on pollution and carbon emissions, allowing a better control of environmental emissions.
- **Heat pumps, air conditioning and refrigeration systems**: the contribution of the Heating, Ventilation, Air Conditioning and Refrigeration and hot water heating (HVACR) to the Green Deal and to the REPowerEU plan is acknowledged by the European Commission.[11] Fluoropolymers are fundamental parts in equipment and machinery used in this sector, since they ensure reliable performance. HVACR equipment is subject to continued

11 European Commission, 'Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions. A Green Deal Industrial Plan for the Net-Zero Age' (2023); European Commission, 'REPowerEU: A plan to rapidly reduce dependence on Russian fossil fuels and fast forward the green transition' (2022) <https://ec.europa.eu/commission/presscorner/detail/en/ip_22_3131> accessed 1 May 2023.

changes in temperature and pressure as well as potentially harsh chemicals (refrigerants). Efficient HVACR systems need to rely on materials that will not fail on demand and will last a long time without degradation, including sealings to avoid leakages. Efficient refrigeration also plays a role in safety since it is necessary for preservation of food and medicines.

3. Environment and Circularity

The extreme stability of fluoropolymers makes them long lasting in the applications where they are used. Most of those applications involve the use of equipment based on processed fluoropolymers, in the form of pipes, tubes, or other pieces. Fluoropolymers extend the life of the equipment and devices where they are used. This significantly contributes to the objectives of a circular economy by reducing the amount of waste that society needs to handle. Replacing fluoropolymers by other materials that would be less efficient in providing the required properties would result in reduced life span, increased need for maintenance and increased amount of waste. Since most of the inferior alternatives are also plastic or rubber materials, a ban on the use of fluoropolymers would force society to cope with significantly increased amounts of wastes of those materials. Here it is useful to underline that based on recent studies, fluoropolymer waste is estimated to represent only 0.14% of all plastic waste in Europe, and <0.01% total waste (Conversio, 2022)[12]; removing such an insignificant percentage of waste coming from fluoropolymers would dramatically increase the overall quantity of waste that would have to be managed. According to the World Business Council for Sustainable Development (WBCSD, 2023), the definition of a circular economy model must take into account 'long service life' of resources, products, parts and materials, and also keeping them in use. Under this perspective, it is unquestionable that fluoropolymers are key contributors to expanding the life span of products and to avoiding the increase of waste streams to society would eventually need to handle and manage.

12 Conversio, 'Fluoropolymer waste in Europe 2020 – End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams' (2022).

The *construction* sector is of particular relevance when evaluating the contribution of fluoropolymers to circularity. Not only do they improve fire safety and energy efficiency of modern buildings, but they also reduce the need for maintenance, replacement and cleaning of structures built with fluoropolymer-based materials. There are a wide variety of modern buildings such as bridges, stadia and domes that have benefited from the use of modern fluoropolymer architectural and construction solutions.

4. Performance

Fluoropolymers are frequently the high-cost solution when top performance is required. Downstream users through their value chains see fluoropolymers as the only material of choice when highly demanding process conditions are required. This is intimately linked to the fact that such value chains usually lead to top of the range end-products in terms of technology or societal progress.

The *semiconductor industry* is a clear example of this. In the production of modern, high-tech microchips, particularly with extremely reduced size (indispensable in the production of modern gadgets such as small mobile phones, laptops or watches), it is absolutely necessary to ensure ultra-pure process stream – going as far as having to ensure absence of impurities to the levels of part per trillion (ppt). Lithographic processes (which are technically extremely complex) involve the use of extremely pure harsh chemicals (acids) which may easily attack process equipment made of other materials, hence liberating residuals of ancillary equipment, which may be passed to the process and ruining the whole production. Fluoropolymers are the only product class that ensure reliable and economic performance in the production of modern semiconductors.

A similar rationale can be established for *electric cables*. As in the case of aircrafts, fluoropolymers are used for insulation of high-volume data transmission cables. Modern technology (e.g., 5G) relies on top performance of the materials involved in the process. Furthermore, data centres involved in the storage and processing of information operate under extremely stringent specifications in terms of fire safety. With their excellent dielectric properties and fire resistance, fluoropolymers are practically the only reliable option to cover the high demands of this industry.

5. Comfort

Certain products that use fluoropolymers and are in direct contact with consumers are marketed for enhanced performance while this seems a disguise for better comfort. Waterproof apparel, cosmetics, ski waxes, bicycle chain lubricants would fall under that category

Frequently there is a thin line separating 'comfort' and 'safety'; for example, heating systems for seats in vehicles are based on fluoropolymer insulated electric cables. It could be argued if this feature is truly necessary for the functioning of society (a question that would likely need to be answered from the perspective that the feature is already available in most cars – hence population would need to face a downgraded in this option); but if the feature is to be maintained, efficient insulation for such cables is necessary in order to avoid fire and to prevent passengers from electrocuting. Similarly, again referring to the automotive industry, fluoropolymers are used for the manufacture of different parts of car equipment, such as door hinges and seat height adjustment bearings. These parts can be regarded as pivot points which are subject to sporadic demand while cars are running, requiring high reliability and very low friction conditions. Not providing an efficient material for this application would take car technology probably different years back and consumers would need to face squeaking and noisy driving experiences, in addition to increased maintenance, reparations and break-downs. While this property may not be necessarily linked to safety, it could be questioned whether European society is ready to accept reduced functionality in these applications which would lead to significantly reduced comfort when driving or traveling by car – or other means of transport.

Where comfort is truly the only reason for use of fluoropolymers (i.e., a 'nice to have' feature), there could be room for debate if society wishes to maintain those uses or not. The most renowned example is the use of fluoropolymers as anti-stick material in frying pans. Again, for this use it could be argued if 'comfort' alone is truly the only reason for use. Frying pans with highly anti-stick coatings allow for reduced use of oil during cooking (linked to a healthier and safer life-style), reduced use of cleaning agents (less chemicals in the environment) and improved durability of the article (helping circularity objectives). Furthermore, uses of frying pans coated with fluoropolymer are safe, because the temperatures required for decomposition of PTFE will not be reached during normal use, and food will burn before such temperatures are reached. In addition to this, in the event that small particles of PTFE may be released due to excessive use, there is no risk for health because such particles will be eliminated by the human body without any possibility of biological interaction, due to its inertness and the fact that they cannot cross biological membranes.[13] Also, those frying pans will eventually end-up in waste plants where they will be treated as metallic waste, therefore under conditions that should not result in environmental concerns. In summary, this use cannot be considered as very dispersive.

In contrast to designed functional or constructive fluoropolymer parts, dispersive uses of fluoropolymers by consumers (e.g., cosmetics, ski waxes, lubricants for bicycle chains), may eventually result in some releases of fluoropolymers to the environment. Again, the key factor is that those polymers are safe due to their nature and not pose a risk to humans or the environment. Still, if the aspiration of society is to not have these materials in the environment, it should be possible to remove such applications from the market without necessarily placing limits to the relevant industrial applications where fluoropolymers are extremely valuable for society, and where they play a significant role in enhancing safety, decarbonization, circularity, innovation and progress. For example, the already existing microplastics restriction under REACH could be a good instrument to force reduction and eventually elimination of such uses.

III. Key Sectors of Application of Fluoropolymers

The true value of fluoropolymers becomes apparent when they are used in industrial applications. Concerns expressed in the PFAS restriction proposal in relation to fluoropolymers are mainly related to low

13 Barbara J Henry, Joseph P Carlin, Jon A Hammerschmidt, Robert C Buck, L William Buxton, Heidelore Fiedler, Jennifer Seed and Oscar Hernandez, 'A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers' (2022) 14 Integrated Environmental Assessment and Management 13, 316–334

Wood, 2021 - Sector of use	Volume 2020 (MT)	Volume %
Transport	15,500	39.2%
Chemical and Power	11,000	27.8%
Electronics	3,500	8.9%
Food and pharmaceutical industry (F&P)	2,000	5.1%
Cookware	2,000	5.1%
Textiles and architecture	1,500	3.8%
Renewable energy	500	1.3%
Medical applications	500	1.3%
Other sectors, not included above	3,000	7.6%
TOTAL	39,500	

volume consumer applications of which the use is dispersive. Such applications are ultimately of very limited interest to the fluoropolymer industry, and claims are already being made that in most of those applications fluoropolymers could be a 'nice to have', but not truly necessary.[14]

Different initiatives on market research related to fluoropolymers have been performed, with the aim to provide volumes used in the different sectors in which these high value products are used.[15] However, it is difficult to get precise data on some of those consumer uses. In some occasions, such information is flagged as confidential.[16] Nevertheless, it is possible to extract valuable information from such market research activities. The following table shows the data that is available from both initiatives.

Differences in the definition of market segments used in various market research reports result in slightly different numbers. Nevertheless, for the purpose of our analysis, the information displayed on volumes clearly reflects that the major share of fluoropolymer uses is in high value, high technological sectors related exclusively to industrial applications. Putting these figures in context, it appears evident that minor consumer applications, such as uses in cosmetics, ski waxes or bicycle chain lubricants are extremely small and therefore of no interest to the fluoropolymer industry, and no significant impact is to be expected if those uses are discontinued.

IV. Conclusions

Fluoropolymers bring high value to society. This is achieved via the combination of extraordinary properties that they offer. Such value is maximised when fluoropolymers are used in industrial applications in high technology sectors. The use of fluoropolymers

14 C&EN, 'How fluoropolymer makers are trying to hold on to their business' (2023) <https://cen.acs.org/materials/polymers/fluoropolymer-makers-trying-hold-business/101/i8?linkId=100000191672537> accessed 1 May 2023.

15 Astute Analytics (2021). Global Fluoropolymers Market. Industry Dynamics, Market Size, and Opportunity Forecast for 2027. April 2021; Wood (2021). PFAS in the treatment of skis — Use, Emissions and Alternatives. Report for Miljødirektoratet/ Norwegian Environment Agency.

16 Wood Group, 'Update of market data for the socio-economic analysis (SEA) of the European fluoropolymer industry' (2022) <https://fluoropolymers.plasticseurope.org/application/files/1216/5485/3500/Fluoropolymers_Market_Data_Update_-_Final_report_-_May_2022.pdf> accessed 1 May 2023.

Astute Analytical, 2021 - Sector of use	Volume 2020 (MT)	Volume %
Industrial equipment: chemical industry	27,700	37.8%
Electronics W&C	9,450	12.9%
Industrial equipment: other	6,500	8.9%
Transport: automotive	5,280	7.2%
Industrial equipment: Semiconductors	4,515	6.2%
Household	3,840	5.2%
Batteries	3,000	4.1%
Construction	3,000	4.1%
Medical & Pharma	2,800	3.8%
Other	2,500	3.4%
Transport: aerospace	2,035	2.8%
Other electronics	1,425	1.9%
Transport: other	1,265	1.7%
TOTAL	73,310	

allows for very high standards related to protection of workers and the general population, efficient development of green energy systems, improved longevity of equipment and articles thus helping the circular economy, and outstanding performance in vital sectors that are critical to ensure Europe's autonomy and technological superiority in comparison to other global economies. In contrast, the value of fluoropolymer in some consumer applications that have been related to potential concerns is very limited and is only related to relative improvement of comfort features.

In addition to this, it should be noted that fluoropolymers have been traditionally the innovative solution of choice by many industries to improve process conditions, either related to safety, development of options to decarbonize the economy or to improve durability of materials. A ban on critical uses of fluoropolymers, or any regulatory initiative that may place barriers to the use of these low risk, high value materials will limit or slow down the speed of innovation in the EU.

Consumer uses, or uses of fluoropolymer-based products by consumers that may be regarded as dispersive (handling of which is understood to be more difficult to control in comparison with activities in an industrial set-up) are of no paramount interest to society, and while fluoropolymers are acknowledged to pose no risk themselves to human health or the environment, limitations to those uses would not result in major negative impact to the European society. Still, the fact that legislation to control such uses is already in place (e.g., via the EU REACH microplastics restriction) suggests that no further action is required, and that eventually those uses will progressively disappear from the European market. If there are societal preferences to limit such uses, a broad restriction of all uses of fluoropolymers via a REACH restriction does not appear to be neither efficient nor justified.

INTERNATIONAL CHEMICAL REGULATORY LAW REVIEW

Although it has been 15 years since the ground breaking REACH regulation came into force and fundamentally changed the way chemical substances are regulated, evaluated and authorised, this dynamic and ever changing policy area merits continuous scrutiny and analysis, including in Europe, Asia and North America. The International Chemical Regulatory and Law Review (ICRL) provides a forum to identify and analyse important legal and regulatory developments in this field on the national, EU and international level. The journal allows experts to report on and discuss important processes that shape the interpretation and application of chemical regulation, in particular those related to biocide law, chemical registration and licenses and the protection of human health and the environment.

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