

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

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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 man-

ufacture, 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 Name(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, 0.000025% by wt. for PFOA].

b. REACH Regulation

The broad REACH regulation governs the manufacture, import, and sale of chemical substances in Eu-

rope.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), perfluorononanoic 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 cooperative 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, mix-

tures 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:

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 for-

ward 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 Commis-

sion 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 California⁵⁰, Maine⁵¹, Maryland⁵², Minnesota⁵³, Oregon⁵⁴, and Washington⁵⁵, 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.

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

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

AFFF.⁹³ Effective from 1 January 2023, the use of fire-fighting 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 pack-

aging, 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, California¹⁰¹ and Vermont¹⁰² 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 pri-

mary 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
<p>25 ppb^a for any individual PFAS.^b 250 ppb for the sum of PFAS, optionally with prior degradation of precursors.*</p>	<p>50 ppm for PFAS with polymeric PFAS included.^c</p>

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
<p>Full PFAS ban with a limited number of (full) derogations. 18-month transitional period following enforcement of regulation.</p>	<p>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.</p>

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.