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Late lessons from early warnings on PFAS

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Steffen Foss Hansen [1] ✉, Carina Theresa Heller Bunde[1], Monika A. Roy [2], Joel A. Tickner[2] & Anders Baun[1]

Achieving compliance with recent per- and polyfluoroalkyl substances (PFAS) regulations in the United States and Europe will require substantial effort and funding by municipal water providers, as well as chemical and product innovation to avoid regrettable substitutions. Despite emerging knowledge of the potential persistence, bioaccumulation and toxicity of these substances already several decades ago, regulatory action has only been taken in the last few years. Here we examine the background for this late regulatory action, whether early warning signs were overlooked, and whether regulatory or market actions could have been taken earlier. We find that problems in defining PFAS as a group of substances, including extrapolating hazard information from perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) to other PFAS substances, have hampered the effective protection of public health and the environment. Moreover, because PFAS chemistry uniquely imparts useful functionality in a wide range of applications, many uses may be hard to replace without either modifying performance specifications for certain applications or carrying out substantial research and development and scaling of safer replacements. Most importantly, regulatory frameworks in the United States and the European Union have not been suited to group-based assessments, but are rather aimed at chemical-specific, case-by-case risk assessment and management. Even in these cases, too little emphasis has been put on using persistency as a crucial early warning property before full evidence of the hazards of individual PFAS compounds was available. We hope that this analysis provides additional insights into discussions and actions on PFAS and contributes to earlier action on other potentially hazardous chemicals and/or chemical classes.

In August 2022, the state of California in the United States banned the sale of beauty and personal care products with 'intentionally added' per- and polyfluoroalkyl substances (PFAS) as of 2025[1]. PFAS have been used extensively in surface coating and protectant formulations in a wide range of applications because of their unique and novel surfactant properties[2,3]. This ban comes after many US states have restricted various uses of PFAS (for example, in firefighting foam and food packaging) to prevent further PFAS contamination of drinking water as well as effects on humans and ecosystems. In 2021, the regional government of Flanders in Belgium ordered the company 3M to shut down production of almost all PFAS substances. This was the first time that such regulatory action on the production of PFAS was taken anywhere in the world[4].

The recent restriction in California was established after the United States Environmental Protection Agency (US EPA) in June 2022 reduced the lifetime drinking water health advisory value for perfluorooctanoic acid (PFOA)[5] from 70 ng l^{-1} to 0.004 ng l^{-1} and for perfluorooctane sulfonic acid (PFOS)[6] to 0.02 ng l^{-1}. The new health advisory levels are based on epidemiological studies published in 2012 and 2018 on the

[1]Department of Environmental and Resource Engineering, Technical University of Denmark, Lyngby, Denmark. [2]Department of Public Health, University of Massachusetts, Lowell, USA. ✉e-mail: sfha@dtu.dk

effects of PFOS and PFOA on serum vaccine antibody concentrations in children[7,8], extrapolated to define a level at or below which exposure over a lifetime is not anticipated to lead to adverse human health effects. The decision to implement a national primary drinking water regulation for PFOS and PFOA is one of 23 actions outlined by the US EPA in its 2019 PFAS Action Plan and the 2023 White House PFAS Action Plan[9,10]. Similarly, other countries have developed strategic plans to address PFAS pollution. For example, the European Chemicals Agency (ECHA) published a highly anticipated proposal in February 2023 for a far-reaching PFAS restriction, including almost all PFAS uses in the European Union and with derogations only for five or twelve years if suitable alternatives are not readily available[11].

Regulations are starting to impact manufacturers. For example, in December 2022 3M announced its intention to stop its manufacturing of all PFAS substances and remove all PFAS from its product portfolio by 2025 (ref. 12). More than 6,500 civil actions have now been filed by government entities and others against PFAS manufacturers for health and ecological impacts[13].

Important efforts to examine and learn from history have been made for other chemical substances. In 2001 and 2013, expert panels commissioned by the European Environment Agency (EEA) published two reports under the heading 'Late Lessons from Early Warnings', in which they investigated more than 30 historical case studies, such as asbestos, polychlorinated biphenyls and irradiation, to identify what was learnt from the lack of early regulatory action and how this could be used to take more proactive measures to protect human health and the environment[14,15].

In this Perspective we utilize the EEA Late Lesson's framework to give explanations for why regulatory action on PFAS contamination seems to have come late relative to the scientific knowledge of the potential effects on human health and the environment. In the following sections we use the historical events related to PFAS regulation (Fig. 1) to discuss whether (1) the lack of scientific evidence on hazard, exposure or risk, (2) limited environmental monitoring, (3) limits to government policies and their implementation or (4) lack of safer, feasible alternatives could explain why today we face global contamination with a group of chemicals long known to be persistent, bioaccumulative, mobile and toxic.

Some of the historical events included in the following sections are compiled from court records. Where no declaration from the named manufacturers in response to allegations or legal action is mentioned, it should be assumed that to the best of the authors' knowledge no such declaration was made.

Early evidence of persistent, bioaccumulative and toxic effects

Early identification of potential harmful effects is a prerequisite for the protection of human and ecological health from harmful chemicals[14,15]. Just three years after PFOA was invented in 1947, 3M found that perfluorobutyric acid (PFBA), a shorter-chain PFAS compared to PFOA, was slightly toxic to mice after oral administration, intraperitoneal and intravenous administration. For instance, the lethal doses that caused 50% mortality were reported to be LD_{50} of 1,001 mg/kg and 804 mg/kg after 72 hours and 1 week, respectively after oral administration[16]. For oral administration, this corresponds to a category four out of five acute toxicity hazard categories when considering the United Nation's Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (https://unece.org/sites/default/files/2023-07/GHS%20Rev10e.pdf). Almost 30 years later, 3M studies showed that PFOA did not degrade at all in a 2.5-month biodegradation study using activated sludge inocula obtained from three waste treatment systems (1978)[17], bioaccumulates in fish (1979)[18], and causes birth defects in rats after ingestion (1981)[19]. In 1970, DuPont concluded that PFAO are 'highly toxic when inhaled'[20], and in the 1990s the company identified increased cancer rates among its workers[21–23] (Fig. 1). For instance, DuPont found a statistically significant elevation in leukaemia and an excess of cancers of the buccal cavity, pharynx, kidney and other urinary cancers among male employees at Washington Works, one of DuPont's factories in West Virginia, United States. The findings were based on an analysis of surveillance data on mortality and cancer incidence from DuPont's company-wide epidemiologic surveillance programme.

Several academic[24,25] and military studies[26–29] during the 1950s and onwards also found evidence of health and environmental impacts related to PFAS. For instance, in 1956 Nordby and Luck[24] studied the interaction of PFOA and human serum albumin (HSA) and found that PFOA has the ability to precipitate HSA and disrupts protein structure and function, which could indicate a hazard. Later, in 1976 Taves and colleagues[25] showed that organic fluorocompounds were prevalently found in the human serum of people not occupationally exposed and suggested that there is widespread contamination of human tissues with trace amounts of organic fluorocompounds derived from commercial products. Experiments on rainbow trout performed in 1974 by Krupp and Martin from the US Air Force Weapons Laboratory first observed that four out of four trout died within 48 hours after having been exposed to activated sludge effluent containing 200 mg l^{-1} FC-200. FC-200 is one form of aqueous film-forming foams (AFFF) used for firefighting. Information on the composition of AFFF is normally considered propriety information, but it has been reported that their total PFAS concentration may have been up to 5% in the past[30]. The trout did not die within 96 hours after exposure to effluent containing other types of AFFF, but all the trout died within 96 hours after exposure to untreated wastewater containing 200 mg l^{-1} AFFFs. Similarly, LeFebvre et al.[27] exposed fry and juvenile Fathead minnows to FC-206 and estimated the 50% lethal concentration (LC_{50}) of FC-206 to be 170 ml l^{-1} for three-week-old fry after 96 hours. LC_{50} is the estimated concentration that causes 50% of the exposed organisms to die after a given time. FC-206 was found to be six times less toxic for juvenile Fathead minnows. In 1972, Peter Goldman from the US National Institutes of Health suggested that compounds containing the carbon–fluorine bond 'pose at least a potential threat to the environment' due to their stability[31]. By 1991, AFFF was considered a hazardous material in a number of US states and the US Army Corps of Engineers argued that firefighting operations that use AFFF must be replaced with non-hazardous substitutes[29]. From historical records, it appears that a significant time gap occurred between the emergence of evidence potential impacts and when public health and environmental authorities began to evaluate the harmful effects of PFOS and PFOA (Fig. 1).

Governments begin to develop conclusions regarding PFAS hazards

The first governmental or intergovernmental hazard assessments of one of the predominant PFAS substances, PFOS, were not completed until 2002, when the Organization for Economic Cooperation and Development (OECD) concluded that PFOS is persistent, bioaccumulative and toxic (PBT) to mammalian species[32]. However, this came after 3M had already announced that they would globally phase out their manufacturing starting in 2001. The OECD noted that one of the problems with PFAS is that it is a group of many substances and that it was not clear whether the hazard concerns for PFOS could be extrapolated to other perfluorinated compounds. For the group of PFAS compounds, it is still for PFOA and PFOS that hazard information is most abundantly available[33].

In their 2002 Draft Hazard Assessment of PFOA and its salts, the US EPA concluded that PFOA is persistent, with a half-life ranging from 1.50 to 13.49 years, and noted its potential systemic toxicity, carcinogenicity, developmental/reproductive toxicity and immunotoxicity associated with the ammonium salt of PFOA[34]. In 2003, the US EPA concluded, in a preliminary risk assessment, that PFOA was linked to developmental effects in laboratory rats, raising concern about the health effects associated with the PFOA and PFOS used in DuPont's Teflon products[35,36].

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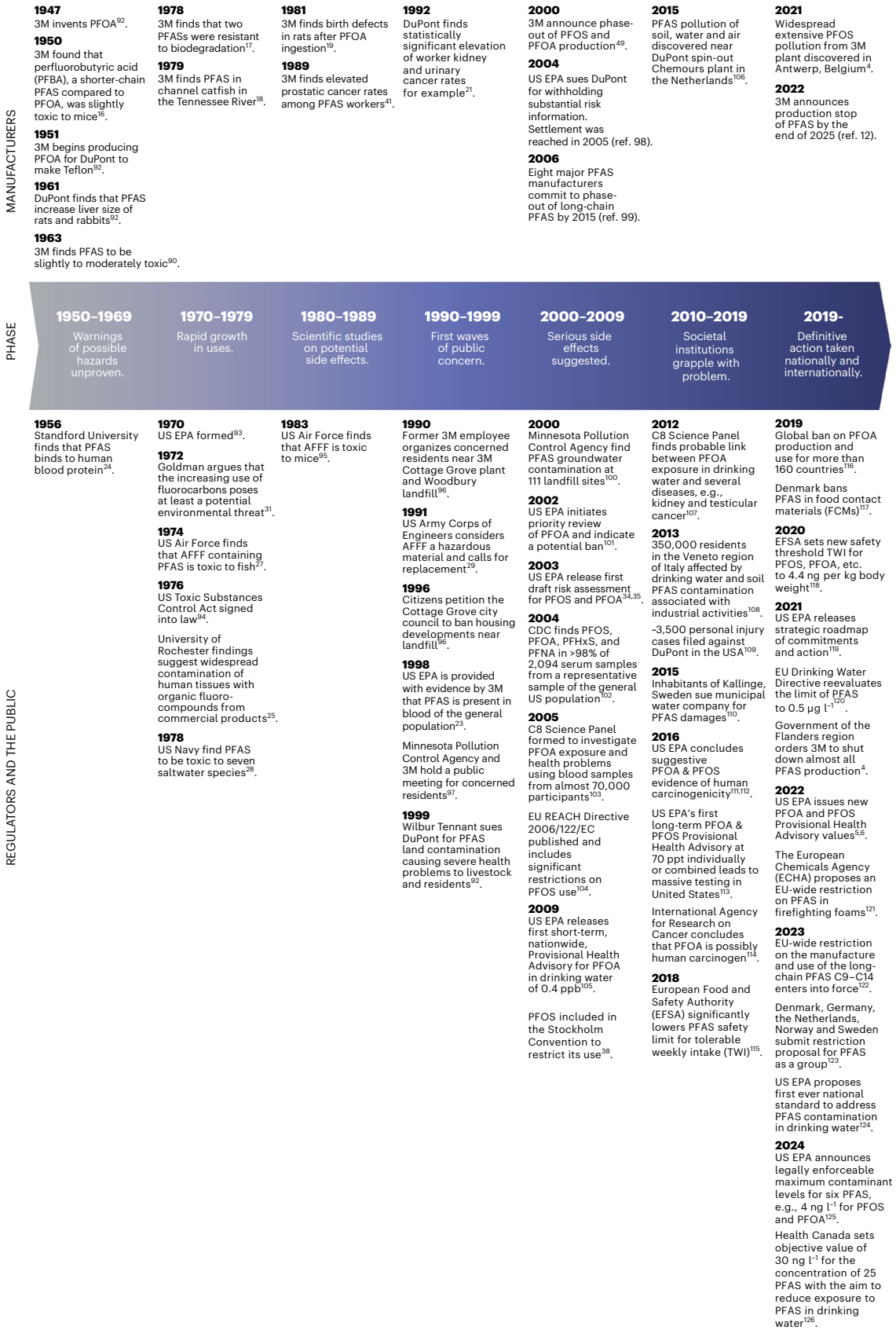

Fig. 1 | Overview of historical PFAS events by decade. Top: information and actions taken by 3M and DuPont. Bottom: reported information and actions taken by regulators and the public. AFFF, aqueous film-forming foams; PFHxS, perfluorohexanesulfonic acid; PFNA, perfluorononanoic acid. Traditionally, such cases follow a process of (1) warnings of possible unproven hazards, (2) rapid growth in uses, (3) scientific studies on potential side effects, (4) first waves of public concern, (5) serious side effects suggested, (6) societal institutions grappling with the problem and rampant public confusion, (7) definitive action taken nationally and internationally and, eventually, (8) litigation about damages and clean-up[14,15,91–126].

In 2004, in an environmental risk assessment prepared for the UK Environment Agency, PFOS was identified as a PBT compound that constituted a risk of secondary poisoning for all ongoing uses as well as to terrestrial and aquatic environments[37]. The hazard assessments completed by the OECD and the UK Environment Agency eventually laid the foundation for the inclusion of PFOS in the 2009 Stockholm Convention to restrict its use globally[38].

More toxic than originally believed

In many historical cases (for example, for lead and mercury), as more is learned about the hazards of substances, more concerns are raised about longer-term exposures to those substances at lower doses[14,15]. In 1977, 3M observed that three PFAS substances caused deaths, liver toxicity, decreased red blood cell counts, weight loss and decreased physical activity in a 90-day subacute toxicity study in rats and monkeys[39]. The 3M researchers called for pulmonary exposure studies and lifetime rodent studies to be completed as soon as possible to predict chronic effects for humans and to '…reasonably assure relative safety of these compounds following long-term exposure'. Such animal and epidemiological studies were completed by 3M in 1987[40] and 1989[41], when it was found that PFOA causes tumours in animals and an increased cancer rate among PFAS workers.

Since 2000, published research on the health and ecological effects of PFAS has expanded substantially. In a PubMed search, only two scientific papers on PFAS and its health effects were found before 2000, in contrast to more than 1,100 papers after 2000[42]. Many of the recent studies associating health concerns with PFAS exposure are now catalogued in the PFAS Health Effects Database[43]. The growing toxicity concerns over the past two decades have progressively led to more stringent PFAS drinking water guidelines and increased PFAS regulations and restrictions[44,45].

Lack of early detection?

Information on exposure levels is crucial for regulatory decision-making and risk-management actions. As already identified, evidence of human exposure to PFAS began to accumulate in the 1970s when DuPont found PFOA in the blood of workers, resulting in the implementation of a monitoring programme[46]. In 1984, DuPont detected PFOA in the tap water of Little Hocking, Ohio, in the United States[47]. However, scientific studies on the environmental distribution of PFAS first emerged only at the end of the 1990s and in the early 2000s. In 1999, Moody and Field investigated groundwater contamination at military firefighting training facilities and found perfluorocarboxylate concentrations ranging from 125 to 7,090 μg l^{-1} (ref. 48). Interestingly, "the persistence of certain FCs [fluorochemicals] and their detection at extremely low levels in the blood of the general population and wildlife" was provided by 3M as one of several reasons for their phase-out of PFOS production in 2000[49].

With enhanced monitoring, the high mobility of some PFAS became evident, and the compounds have now been detected in humans, water, soils, and marine and land mammals globally. In the environment, sampling in remote areas like the Arctic, North Atlantic and West Greenland has shown increasing concentrations of PFAS in large marine mammals since the 1980s[50–52], and some of the highest known concentrations have been measured in polar bears[50]. Recently, researchers reported that PFAS have been detected in wet deposition collected between 2010 and 2022 all around the world, including Antarctica and the Tibetan plateau[44].

Lack of scientific consensus about risks?

Lack of scientific consensus about chemical risks has often been used as a reason for delaying regulatory action[14,15]. The hazards of PFOS were established with the 2002 OECD hazard assessment, which included a consensus-based process involving experts from OECD member countries[32]. For PFAS substances overall, there have been several scientific consensus statements created in the past decade. In the first, the 2014 Helsingør Statement, scientists expressed concerns about the substitution of long-chain PFAS for shorter chain—and less investigated—PFAS[53]. The second was the 2015 Madrid Statement, which proposed 22 actions to be taken by stakeholders (for example, clear legislation that only allows PFAS for essential uses) and was signed by more than 250 scientists[54,55]. In the third, the 2018 Zürich Statement, scientists proposed several additional actions that needed to be taken, such as cooperation on a group assessment of PFAS, ranging from hazard assessments to socioeconomic impact assessments of the lifecycle of PFAS[33]. Collectively, these consensus statements have been cited widely in the public media, scientific journals and background documents that support regulatory action[56–58]. Although scientific consensus about the the human health and environmental risks of PFOS and PFOA have existed for nearly two decades, evolving consensus regarding the risks associated with the entire class of PFAS is more recent. There is still debate about the extent to which the hazard information on specific PFAS substances can be extrapolated to other subgroups of PFAS and how to group different PFAS for risk assessment and regulatory purposes[59]. Nonetheless, regulators and science advisory bodies in the United States (for example, in Massachusetts and California), Europe and the OECD have defined PFAS broadly based on evidence of hazards[11,60,61].

Lack of safer, feasible alternatives?

Because of the unique nature of the carbon–fluorine bond, PFAS chemistry is widely used in applications ranging from coatings to surfactants, polymers in wires and cables, and refrigerant gases. PFAS are costly to produce and are generally used in applications where they impart important function and performance. Researchers have identified more than 200 uses in 64 use categories and 21 industry sectors for more than 1,400 individual PFAS substances, with key sectors including aerospace, electronics, automotive, textiles and packaging[62].

A lack of safer, feasible alternatives can be a reason for limited action on chemicals of concern[14,15]. However, research on chemicals of concern, such as PFAS, often focus on an ever-more nuanced understanding of the risks rather than on the development of solutions[63]. A range of studies have evaluated PFAS alternatives in a number of applications[64]. Substitution may be easier or more challenging depending on the application, but almost inevitably takes time and resources[65]. For example, alternatives now exist for durable water repellency in textiles, although these took years to develop and implement[66]. However, PFAS substitution in the electronics sector may be more complicated, with barriers including the costs of research and development and reformulation, lower or different performance of substitutes, procurement requirements, limited information on uses and alternatives, validation and certification requirements for alternatives, and slow regulatory review of substitutes. Some of these barriers exist for PFAS substitution in semiconductor manufacturing, where PFAS play a critical role in performance. Nonetheless, cases exist of companies successfully developing alternatives, for example, for safer etching products without PFAS[67].

Additionally, it is important that alternatives are safe for health and the environment. An early response to concerns about PFOA and PFOS (which are both 8-carbon chains or C8) was to move towards the use of shorter-chain PFAS; however, these turned out to be regrettable substitutes[68,69]. For other potential alternatives, concerns have been raised about cyclic siloxanes due to their toxicity and persistency[70]. Similarly, engineered nanomaterials have been suggested as PFAS alternatives for a number of applications, but there is a general lack of data assessing their environmental fate and effects[71,72].

In some cases, the functionality of PFAS may not be necessary or their use is over-prescribed. Cousins and colleagues have proposed the concept of 'essential uses' to identify those uses of PFAS that are not necessary for health, safety and the functioning of society[73].

Table 1 | Criteria for precautionary action based on an analysis of more than 30 historical cases of lack of precautionary action and the year for which data on these criteria first appeared for PFOA and PFOS

Criteria for precautionary action[15]	Year that data to support precautionary action for PFOA and PFOS first appeared
1. Intrinsic toxicity/ecotoxicity data	1963[90]
2. Novelty (that is, where there is a low 'knowledge/ignorance ratio')	1947[2,3]
3. Ecological or biological persistence	1950[16]
4. Potential for bioaccumulation	1978[17]
5. Large spatial range in the environment, for example, potential for global dispersion	1979[18]
6. Seriousness of potential hazards	1981[19]
7. Irreversibility of potential hazards	1977[39]
8. Analogous evidence from known hazards	1972[31]
9. Inequitable distribution of hazardous impacts on particular regions, people and generations	1981[19]
10. Availability of feasible alternatives	Increasing since mid-2000s

Similarly, taking a 'fit-for-purpose' approach to evaluating performance may lead to more available alternatives that perform sufficiently, rather than expecting equivalent—and perhaps unnecessary—performance to the incumbent chemistry[74].

Was the precautionary principle adequately applied in the case of PFAS?

Since the early 2000s, scientists and others have repeatedly called for application of the precautionary principle (action in the face of growing evidence, yet continued uncertainty) to 'the PFAS case'[74–81]. Although early calls applied only to PFOS and PFOA, these have been extended to cover the entire class of PFAS[33,82,83]. Compared to some other chemicals and chemical groups of concern, one could argue that regulatory and market action on PFAS as a class—based on growing published evidence starting in the early 2000s—has been relatively quick once concerns were raised. For example, in the case of leaded petrol and asbestos, regulatory action took between 50 and 100 years[14,15,84]. Yet, the more recent case of 6PPD (*N*-(1,3-dimethylbutyl) -*N*'-phenyl-*p*-phenylenediamine), an anti-ozonant in tyres that, when released into the environment, is highly toxic to coho salmon, shows that regulatory action can quickly follow evidence of impact, particularly when that impact is clear and acute[85].

In their work, the EEA has identified 12 criteria for action, of which the ten relevant for PFAS are listed in Table 1. Data to trigger these criteria began to appear several decades ago for PFOA and PFOS.

The EEA analysis identified five early warning signs, which, if ignored, can have severe consequences later on. These are novelty, persistency, mobility, bioaccumulation and potential irreversible human health and environmental impacts[14]. For PFOA and PFOS, all of these were triggered early on. The carbon–fluorine bonds that make PFAS substances unique with respect to function and applicability in products cannot be broken in humans or the environment. This inherent persistency is the one warning sign that is consistently triggered for all PFAS compounds independently of what is known about their individual hazardousness. The vast number of different PFAS substances makes substance-by-substance assessment and individual regulation impossible[33,57]. Therefore, it has been argued that persistency alone (or in combination with mobility) is sufficient for evaluating and regulating PFAS as a single chemical class[82,83]. If such an approach is adopted, exposure will not continue for long periods of time (decades to centuries) even if the persistency of a given substance is underestimated[84,85]. If persistency is eventually considered sufficient for triggering risk-management actions (that is, in lieu of action based on full risk assessments), it could have profound implications for early action to prevent problems with other groups of chemicals and could speed up regulatory decision-making on existing and emerging chemical contaminants[83,86–88].

Conclusion

PFAS is now considered a global contaminant and one of the highest priority chemical regulatory issues for governments today. The mechanisms in place to ensure early detection, risk assessment and management were triggered for PFAS long ago. However, these were not acted upon, and widespread water contamination ensued, in part due to the following reasons:

1. Regulators did not have early access to the toxicological and exposure studies. Even when early evidence of hazards and risk were made publicly available, it was not translated into action by authorities. Instead, they relied on voluntary measures taken by some manufacturers.
2. Given the sheer number of PFAS substances, there was a lack of consensus about how to extrapolate known risks of PFOS and PFOA to other PFAS and how to define the class of PFAS substances. Furthermore, regulatory regimes were not generally designed for assessing and managing groups of hazardous chemicals. Instead, they relied mainly on one-by-one chemical risk assessments. Consequently, many US states and European countries have taken actions on individual PFAS.
3. Regulatory frameworks and systems were designed to require evidence of significant risks (along with a balancing of costs and benefits), which requires a detailed analysis of hazards and exposures, as well as public consultation periods, before risk-management measures are proposed. Measures resulting from these frameworks may take years to implement. Only in the past decade have EU and US government agencies begun to implement precautionary policies based primarily on evidence of persistency and bioaccumulation or class-based policies based on evidence on a few chemicals of the class (such as PFAS or bisphenols), extrapolated to the whole class.
4. PFAS serve important functions in critical applications, and alternatives may currently not adequately provide similar functionalities. However, without regulatory structures in place to adequately incentivize investment in the development of non-fluorine-based alternatives, many manufacturers switched from C8 PFAS to C6 alternatives thinking they were safer, when in fact they were not. Concepts and tools such as alternatives assessment and Safe and Sustainable by Design[89] were not required or heeded to guide the transition towards safer, but effective, alternatives.

Today, it may be easy to blame only PFAS manufacturers for the widespread public health and environmental issues, but the reasons for delayed action are more complex. Laws regulating toxic substances that would have required disclosure of information on PFAS hazards (and the agencies to implement them) did not exist until the 1970s. A major wave of scientific research on PFAS did not emerge until the late 1990s, as manufacturers withheld their early studies, knowledge, insights and (eco)toxicity data from regulators, the scientific community and the public. There was also little scientific experience with assessing classes of chemicals. Regulating chemical classes was new territory for government authorities tasked with implementing regulatory programmes focused on chemical-by-chemical assessments, with risk-management actions following such assessments. An important lesson is that it is difficult to address chemicals of concern—particularly for critical applications—without a supply of safer and feasible

alternatives. Regulatory action is a critical driver for innovation, but it needs to be supplemented with funding for research and development and technical support for the adoption of safer substitutes. The case of PFAS highlights important lessons for designing more effective scientific-policy regimes that prevent chemical contamination while driving innovation in safer and more sustainable chemicals and materials.

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Additional information
Correspondence should be addressed to Steffen Foss Hansen.

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