Policy Position

December 2021

Risk-based regulation for per- and poly-fluoroalkyl substances (PFAS)

PFAS play an important role in some vital products that improve quality and longevity of life. With that recognition, concerns are increasing across the world about the adverse health impacts of PFAS, to humans and wildlife. All PFAS are persistent. All uses of PFAS should be assessed, using specific risk-based regulation based on sound science, with better environmental (bio)monitoring and grouping approaches to characterise exposure and hazard, respectively. Investment now in new scientific approaches, and in the skills base for the provision of scientific advice, will enable the health and environmental risks of groups of PFAS to be better understood. Release of toxic PFAS into the environment must be controlled in the near future. We need to know as soon as possible which of the many hundreds of PFAS are toxic and which are not. It is possible to achieve effective PFAS-specific regulation, to retain the safe and sustainable uses of PFAS in products and processes that are considered vital to future innovations of benefit to society. A ban on all PFAS as a group is neither practical, necessary, nor achievable. However, defined PFAS groups that are shown to present an unacceptable risk to humans or wildlife must be restricted or removed. This policy position provides a thought-starter for discussing a risk-based framework for PFAS regulation, to maintain high standards of health, safety, and environmental protection, and promote effective global action to reduce pollution.

Summary points

- **Based on concerns around unquestionable persistence of PFAS and potential toxicity of some PFAS, governments and chemical agencies need to regulate PFAS urgently all across the world.**
- **With experienced regulators and an excellent science base, the UK should take a leading role on developing risk-based PFAS regulation, using a set of sound principles for the management of chemicals in the environment as informed using state-of-the-art scientific evidence.**
- **We advocate taking a starting position that balances precaution, risk and impacts, given the scientific uncertainties and unknowns surrounding the potential for insidious long-term toxicity from some PFAS.**
- **Governments could involve citizens in a multistakeholder group – we introduce the concept of a 'PFAS Jury' to decide if PFAS uses are deemed as 'vital' or 'highly desirable'; this could help prioritise further urgent efforts**
- **For those PFAS which are defined as 'vital' or 'highly desirable' by wider society, human and wildlife exposure should be managed and reduced to levels of societally 'acceptable risk', informed by the best science.**
- **To address the safety data gaps for PFAS, new approach methods (NAMs) in exposure and toxicology science are emerging; global collaborative efforts, to address data gaps and share data, should increase to minimise any future animal testing and seek harmonisation of new evidence.**
- **Governments should decide whether PFAS deemed neither 'vital' nor 'highly desirable' by wider society should be deprioritised for science evaluation, and those of greatest risk phased-out or restricted without delay.**
- **We propose a potential framework for discussion based on a 'traffic light' approach for resulting action on PFAS, where grouped substances are prioritised for action by a central regulatory agency, based on both their functional need in society and highest risks of potential harm.**

Building Blocks, Challenges and Outcomes of a Proposed Framework for Risk-Based Regulation of Per- and Poly-fluoroalkyl Substances (PFAS)

The concerns relating to PFAS are real; PFAS must be regulated via risk-based evaluation, urgently, to prevent a potentially damaging and intractable issue now and for the next generations, with suitable controls put in place. A summary of a stepwise framework is presented in Figure 1, to consider how regulatory action and scientific efforts could evolve hand-in-hand to support urgent and effective risk-based control of toxic and persistent PFAS.

The key scientific challenges are:

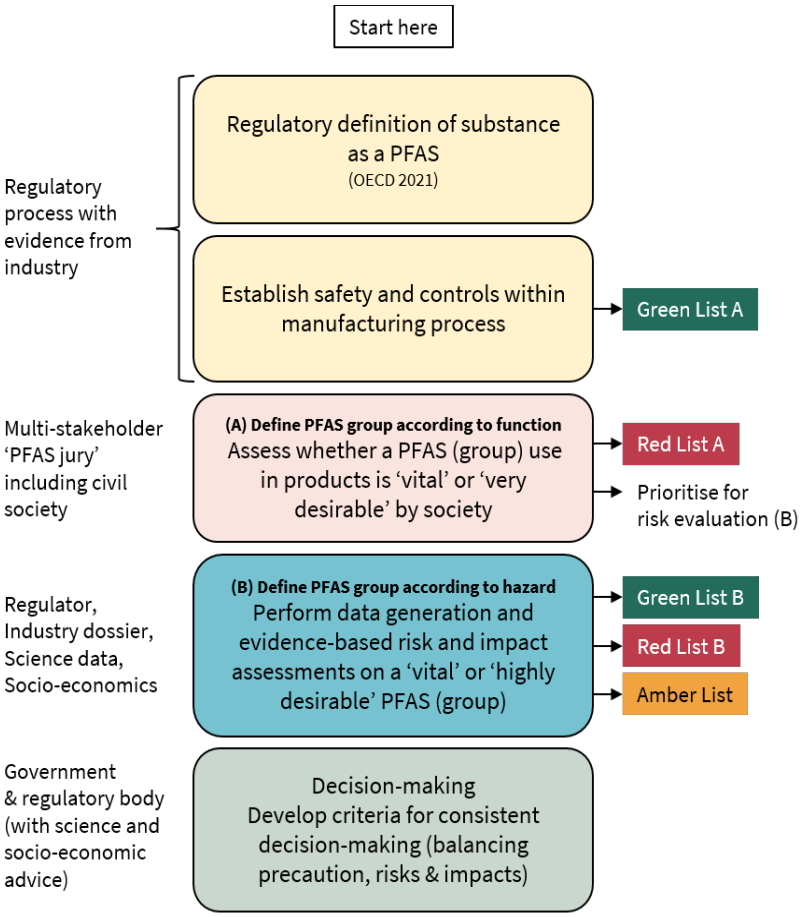
i) The data gaps and unknowns are extensive on the toxicology for hundreds of PFAS

ii) The data on real exposure levels to PFAS in the environment and in human bodies is sparse

iii) Addressing these scientific gaps using traditional toxicology and exposure assessment approaches for individual PFAS would take decades, be too costly and involve too many animals; we need investment in new scientific approaches

iv) To guide the science, a collaborative steer is needed from wider society to focus efforts on those PFAS that are most important for the future benefit of society. A distinction is made between scientific analysis, regulatory considerations and decisions taken by government with the input of civil society.

v) For PFAS with data, scientists can do a risk assessment now, and consideration of how vital the PFAS is can come after risk assessment has shown a moderate to high risk; but scientists cannot take the decision on what is 'acceptable risk'.



(A) Grouping based on sector, function and product types
(B) Grouping based on science, hazard and risk

Potential outcomes from the framework:

Green List A – occupational and environmental release can be strictly controlled for a PFAS used only in specified manufacturing processes – the PFAS is safe to use for the permitted manufacturing process. NB. PFAS that cannot be strictly controlled are treated in the framework the same as PFAS in end-products.

Green list B – PFAS use in end-product is considered 'vital' or 'highly desirable' by wider society, data on safety are available, risks are evaluated and designated no/low concern – PFAS is safe to use for the permitted processes and products.

Amber List – PFAS use in end-product is considered 'vital' or 'highly desirable' by wider society, data on safety are available, risks are evaluated and designated medium or high concern – restricted use is allowed until alternatives to PFAS are available and targeted environmental (bio)monitoring is performed.

Red List A – PFAS use in end-product is determined as not 'vital' or 'highly desirable' by wider society – recommendation by a 'PFAS jury' to the regulator to phase out PFAS use, no requirement for further safety data to be generated.

Red List B – PFAS use in end-product determined 'vital' or 'highly desirable' by wider society, but data on safety are not available, the risk is not acceptable without any data – PFAS use is phased out.

Figure 1: *The building blocks and potential outcomes of a science-informed, risk-based framework for action on PFAS*

1. Introduction

The term PFAS (as defined by the Organisation for Economic Co-operation and Development (OECD), 2021 – see section 4 below) represents a large group of thousands of fluorinated chemicals used globally since the 1940s in a multitude of different products and processes for their unique water-, oil-, heat- and stain-resistant properties. However, due to their high stability in the environment and resistance to biodegradation, all PFAS are persistent, and many are highly mobile in global waters. PFAS are present in groundwater, freshwater systems, the marine environment, in wildlife and in our human bodies. We do not truly know the harm that may be evolving as there are many scientific evidence gaps. PFAS have been associated with adverse human health effects, and effects in wildlife, in exposed populations following localised pollution events. Regulations aiming to control exposure to PFAS and mitigate the risks are now emerging around the world to prevent potential harms from accumulative pollution from multiple chronic and diffuse sources.

2. Function and uses of PFAS

PFAS are a large group of more than 4,700 highly fluorinated substances with a carbon backbone, produced since the 1940's and known for their superb and unique water-, oil-repellent and stain-, heat-resistant properties. PFAS are used in wide-ranging and specific applications[1] such as hydraulic fluids, biocides, flame retardants, fire-fighting foam, floor polishes, construction materials, protective clothing, food packaging, heat-resistant non-stick cooking surfaces, medical devices, and insulation of electrical wires, to name a few. Typically, PFAS have not included fluorinated gases (F-gas) (e.g. used as refrigerant gases) but these could now be included under the broad scope of the OECD 2021 definition. Many PFAS are expensive to manufacture and are produced in low amounts in niche and very specific applications.

A detailed list of examples can be found in Table 1.

Table 1: *Major properties and industrial applications of PFAS[1]*

Industry/Application area	Key properties	Typical uses	Typically used PFAS*
Chemical/petrochemical industry	Chemical resistance Good mechanical properties Thermal stability Cryogenic properties	Gaskets, vessel liners, pumps, valve and pipe liners, tubing, coatings, expansion joints/bellows, heat exchangers	PTFE, PFA/MFA ETFE, ECTFE FEP FKM, FFKM TFE-P
Electrical/electronic industry	Low dielectric constant High volume/surface resistivity High dielectric breakdown voltage Flame resistance, Thermal stability Low refractive indices	Wire and cable insulation, connectors, optical fibres, printed circuit boards	FEP, PTFE, PFA, MFA ETFE, ECTFE PCTFE amorphous FP
Automotive/aircraft industry	Low coefficient of friction Good mechanical properties Cryogenic properties, Chemical resistance Low permeation properties	Seals, O-Rings, hoses in automotive power steering, transmissions, and air conditioning, bearings, sensors fuel management systems.	FKM, PTFE FFKM THV

Industry/Application area	Key properties	Typical uses	Typically used PFAS*
Coatings	Thermal/weather stability Low surface energy Chemical resistance	Cookware coatings, coatings of metal surfaces, powder coatings, waterproof clothing	PTFE PVDF, ETFE FEVE, PFA
Medical	Low surface energy, stability, purity Excellent mechanical properties Chemical resistance	Cardiovascular grafts, heart patches, ligament replacement, packaging films for medical products	PTFE, PCTFE
General architectural/fabric/ film applications	Excellent weatherability Flame resistance Transparency Low surface energy Barrier properties	Coated fabrics and films for buildings/roofs, front/backside films for solar applications	ETFE, PTFE, PVDF PCTFE, PVF, THV
Polymer additives	Low coefficient of friction Flame resistance Abrasion resistance Antistick properties	Polyolefin processing to avoid surface defects and for faster processing. Additives for inks, coatings, lubricants, anti-dripping agents	THV, FKM PVDF, PTFE
Semiconductor industry	Chemical resistance High purity Antiadhesion, insulation, barrier properties Thermal stability	Process surfaces, wafer carriers, tubing, valves, pumps and fittings, storage tanks	PFA, ECTFE PCTE, PTFE amorphous FP
Food packaging	Chemical resistance, Excellent mechanical properties, barrier properties	Packaging films for portioning, handling, transport, improving shelf-life	PTFE, PCTFE
Energy conversion/storage Renewable energies	Chemical/thermal resistance Ion-transportation High weatherability High transparency Corrosion resistance	Binder for electrodes, separators, ion-selective membranes, gaskets, membrane-reinforcements, films for photovoltaics, coatings for windmill blades	PVDF, Fluoroionomers (PFSA), THV, ETFE ECTFE, PTFE, FEP PVF

*Abbreviations –
ECTFE Ethene–chlorotrifluoroethene copolymer
ETFE/ET Ethene–tetrafluoroethene copolymer
FEP Fluorinated ethene–propene copolymer
F(F)KM Fluoroelastomers, perfluoroelastomers
MFA Methylfluoroalkoxy copolymer
PCTFE Polychlorotrifluoroethylene
PFA Perfluoroalkoxy/propylfluoroalkoxy copolymer
PTFE Polytetrafluoroethylene
PVDF Poly(vinylidene fluoride)
PVF Poly(vinyl fluoride)
TFEP Tetrafluoroethene–propene copolymer
THV Tetrafluoroethene–hexafluoropropene–vinylidene fluoride terpolymer

Many important sectors of the economy are end-users of PFAS, such as telecommunications, aerospace, automotive, building and construction, electronics, medical devices, etc. As there are not always suitable alternatives for practical applications of many PFAS, banning PFAS from use as a class could cause significant disruption to large sectors of the global economy and the future of innovative products that could benefit human quality of life and longevity.

3. What is the concern about PFAS?

Humans and wildlife are exposed every day to hundreds of natural and man-made chemicals from products and their environment, usually with minimal attributable adverse effects thanks to the effective regulation, risk management of hazardous chemicals and the due diligence of responsible industries. PFAS are unique in relation to other general industrial chemicals because of their unusual bio-persistence, broad use at low levels in niche applications and regulation that is perhaps not as effective as it might be to identify toxic PFAS.

PFAS predominantly contain carbon, fluorine, and hydrogen atoms. The carbon-fluoride bond is one of the strongest in nature, making PFAS highly persistent, resistant to biodegradation and potentially bio-accumulative. PFAS released into the environment, can contaminate soil and drinking water sources for years and have been found in surface waters such as rivers and lakes[2,3] and in the human body[4]. Issues are not just local, but once in the environment, PFAS can travel the globe from source to anywhere in the world[3]. As well as evidence of biological and environmental persistence, there is increasing evidence of toxicity and adverse health effects in humans[5] from some PFAS, particularly following direct exposure pollution incidents.

Often the toxic hazard characterisation data are not available to show how toxic a particular PFAS might be, and there is a wide variation in properties across different groups of PFAS. Concerns are being raised globally about the known and potential adverse effects of long-lasting PFAS on human health and the environment. PFAS are used in everyday consumer products and evidence as to whether exposures lead to transfer and uptake into human blood circulation is not available in most instances.

The scientific community are concerned that if growth in the use of PFAS in products continues unchecked or low-level releases into the environment continue to go unmanaged for the years and decades ahead, people's bodies and those of wildlife will continue to accumulate PFAS and harmful effects could emerge in wider populations. We need to better characterise the potential hazards associated with PFAS and assess the risks, and most importantly this needs to be done in a timely way.

4. How have PFAS been used worldwide for decades without needing full safety evidence?

PFAS have been in use globally for decades since the 1940s and many were used prior to the implementation of safety testing. Widespread chemicals regulations came into effect during the 1970s and 80s and the EU REACH chemicals regulation commenced in 2004. Some PFAS are polymers and have, therefore, been exempt from EU REACH as substances of intrinsic low concern due to low bioavailability. Many newer PFAS inventions, of which there are thousands of distinct chemical analogues, are manufactured, imported, or used at amounts lower than 1 tonne per annum (tpa) and therefore, minimal data are required by regulation. Based upon the Environment Agency (England & Wales) report (2021)[6], "approximately 100 individual PFAS are supplied to the UK market in amounts greater than 1 tonne per year. However, this may not include all PFAS in use, as [UK REACH] registration is not required for PFAS manufactured or imported below the threshold of 1 tonne per year".

Evidence on toxicity, bioaccumulation and environmental persistence has been focused on some individual PFAS chemicals, such as PFOS (perfluorooctane sulfonate) and PFOA (perfluorooctanoate). Over the decades more and more 'alternative' PFAS substances have been created unchecked and unmonitored. This now creates a difficult legacy challenge for regulators as it would be time and resource intensive to test and

evaluate all the individual PFAS on the market using traditional approaches to toxicity testing. New toxicological and biomonitoring methods are emerging and could in principle address the data gaps, combined with new regulatory frameworks, to address the risks and impacts to society and the environment and hence help regulators and decision-makers to take pragmatic action.

5. OECD definition of PFAS for regulatory application

To bring consistency and hopefully global harmonisation to the task, a credible and workable definition is needed. A carefully crafted definition for PFAS was developed by the OECD in 2021[7], removing earlier ambiguities in previous definitions. This OECD definition aims to provide a standardised system that can be used for systematic characterisation and create a globally harmonised system of regulation.

The OECD 2021 definition

"Any fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e. with a few noted exceptions, any chemical with at least a perfluorinated methyl group ($-CF_3$) or a perfluorinated methylene group ($-CF_2-$) is a PFAS"

Crucially, compared to previous definitions used, this OECD definition was extended to include complexes without the perfluorinated methyl moiety ($-CF_3$) and complexes with aromatic side chains, as long as a perfluorinated methylene group ($-CF_2-$) is present. We support a globally harmonised use of this definition and the reconciled terminology described in the OECD report[7]. Within this policy position we have used the term PFAS to mean the compound or compounds under this terminology that share the same trait above for having a fully fluorinated methyl or methylene carbon moiety as defined by the OECD definition.

Given the diversity of PFAS, there is the ability to continually reinvent multiple PFAS analogues of the same beneficial and functional properties at low tonnages, notably <1tpa thus negating any legal requirement to generate meaningful safety evidence under UK/EU REACH. Regulating every PFAS individually will result in a 'chemical whack-a-mole' i.e., once one PFAS is banned/restricted, another slightly modified PFAS can pop up and take its place in a product. This leads to the inevitable pitfalls of regrettable substitution and makes regulation ineffective.

There have been suggestions[8] of using persistence alone as a criterion for regulation. However, with current knowledge, we believe such indiscriminate action could lead to unnecessary damage to very beneficial industries and ban highly desirable and very useful, some may say vital, products from the market. Such products could be fundamental to quality and longevity of life and economic prosperity, and in reality, pose little or no risk to health and the environment. As all PFAS are persistent, grouping approaches may be useful to identify the more toxicologically benign and harmful classes of PFAS and assess bioaccumulation. New PFAS are continually emerging in the market, an accurate estimation of the number of PFAS in use remains elusive. We can expect groups to change and evolve over time.

6. The complexity, gaps, and uncertainties in PFAS science

Understanding how PFAS exposure can affect biological function and cause adverse effects in organisms is a complex and uncertain area of science involving chemical, toxicological, and epidemiological evidence. Developing harmonised, pragmatic and science-based regulation, where risks and benefits for people and the environment from PFAS can be managed, is proving challenging and taking too long, as key data gaps remain.

PFAS chemicals occur in solid (e.g., fluoropolymers), liquid (e.g., fluorotelomer alcohols) and gaseous (e.g., hydrofluorocarbon refrigerants) forms, each having different physical and chemical properties. However, from the evidence to date, the intrinsic hazards they pose are not solely related to their physical nature. Therefore, a simple grouping approach using only physical form would be inadequate. Chemical and toxicological properties, exposure parameters and their fate in the environment and in the bodies of humans and wildlife may contribute to grouping approaches. To date, however, the basic fate and behaviour of PFAS in the human body remains uncertain.

Case Study - Data gaps in perfluorooctanoic acid (PFOA) half-life

The data gaps in our understanding of PFAS is exemplified by the challenging conundrum that exists in estimating PFOA half-life once in the human body i.e., how long it takes to clear 50% of the circulating substance from the body into urine/faeces. Values have ranged from less than a year to 14.9 years based on various human biomonitoring studies. The single clinical study on this by Campbell et. al. 2016[9] gave an estimated half-life of 120 – 220 days; human observational studies provide a range of values from 1.2 years to 14.9 years[11]. Another estimate of PFOA half-life is ~1.5 years by Xu et al. 2020[10] where background exposures were subtracted out, although the authors did not measure other potential sources of exposure and confounders.

The review paper by Dourson & Gadagbui (2021) [11] explored the likely causes of this discrepancy. The clinical study[9] is well conducted with numerous monitoring times but is focused on a limited population of patients in various stages of cancer who experienced a higher oral dose of PFAS during medical treatments than what might be expected in a normal human population exposed to PFAS say from drinking water or everyday products. Several of the observational studies were conducted in worker populations that have higher than background exposures. The differing estimates of half-life in human observational studies may be the result of different or multiple exposure routes, exposure pathways or inter-individual differences – the influences of which remain largely unknown. Additional thought is needed in determining which of the various human studies are most appropriate for estimating PFOA half-life. It is possible that arriving at a single value may remain difficult for PFOA half-life and a kinetic profile describing the fate of the substance in the body with time may be more useful.

7. New approach methods for addressing the toxicological hazard and exposure data gaps

The choice of whether to use a 'persistence only' or a 'risk-based' approach (considering persistence, toxic hazard, and exposure/bioaccumulation) to regulation of PFAS defines the nature of the scientific research needed to make due progress i.e., the former requires a low level of new science, the latter requires a more considerable scientific programme and the resources to implement. The application of science, however, can help to support innovation and control use of vital PFAS for the benefit of society. Care is needed in defining the most appropriate scientific research and data generation, as developing a traditional toxicology testing programme (e.g., as per EU REACH testing guidelines) to address all the scientific gaps would be insurmountable and lead to a large increase in animal testing for PFAS that would likely take decades. The development of non-animal testing approaches and new approach methods (NAMs) is a scientific strength in the UK, with the National Centre for the 3R's established in 2004 (https://nc3rs.org.uk). The US EPA has chosen to adopt NAMs as the main basis for addressing hazard data gaps for PFAS, and to attempt categorisation[14].

Investment into evaluating the safety of PFAS is imperative if society is to continue using vital PFAS chemicals in a safe and sustainable way in everyday and innovative new products. Given the many potential sources of exposure to PFAS, defined exposure models may be extremely conservative. It is better

to actually monitor levels of PFAS in the environment (freshwater and marine waters), and in the blood/tissues of humans and wildlife over time to monitor trends of real levels of exposure, e.g., monitoring PFAS levels in drinking water sources and in human serum. Such monitoring is routine in the US i.e., in programmes such as NHANES (National Health and Nutrition Examination Survey), which has monitored PFAS in human participants[12] for more than 20 years using a standardised analytical method. Investment is needed in all parts of the world to routinely monitor the levels of PFAS compounds in the environment and in people. The expectation is that levels could in fact be low, but we have limited evidence to prove it, and given the persistence we may be wrong in that assumption.

Case Study – US EPA's scientific approach to PFAS testing

The United States has introduced PFAS Action Act of 2021[13] delegating responsibility to the US EPA to regulate PFAS and to determine whether to designate all PFAS as hazardous substances individually or in groups. The US Environmental Protection Agency (EPA) aims to reduce its mammalian study requests and funding by 30 percent by 2025 and eliminate such studies by 2035. In its objective to establish New Approach Methodologies (NAMs) that fill critical information gaps, the EPA aims to develop a suite of assays for investigating the biological activity of PFAS chemicals and provide peer-reviewed guidance on their use. For this the EPA assembled a PFAS Chemical Library, procured 430 unique PFAS substances, and devised specialised categories[14] to assign related compounds into based on chemical structure. The EPA then selected 150 representative PFAS chemicals from each category that best translate to the wider PFAS landscape. Toxicological responses, such as developmental toxicity, immunotoxicity, mitochondrial toxicity, neurotoxicity, endocrine disruption, and general toxicity, were measured using specific *in vitro* assays as indicators of mode-of-action relevant biological activities.

To establish scientific confidence in NAMs, the EPA aims to characterise the scientific quality and relevance of existing animal tests, then develop a scientific confidence framework to evaluate the quality, reliability, and relevance of the *in vitro* NAMs to known end effects in intact organisms. The insights gained will be used to create a harmonised scheme of grouping PFAS to enable health-based guideline values and risk assessments to be defined for different classes of PFAS with similar toxicological effects. To achieve this, a computer-based categorisation method, PFAS ToxPrints[15] has been developed, which grouped the 150 tested PFAS into 34 structural categories based on their *in vitro* effects, covering more than 90% of PFAS tested. It is anticipated that targeted animal studies may still be needed to test representative PFAS belonging to each of the identified categories e.g., to assess for potential cancer and reproductive/developmental effects. However, this number of animal studies would be far lower than would be expected if all PFAS were being tested individually in the absence of the ToxPrint categories and using a traditional paradigm.

To support the advancement of scientific knowledge, foster innovation and global collaboration and develop a strong skills base, for PFAS science and other challenging issues for chemicals used in society, we urge the UK government to invest in a Science Hub for Applied Research in Chemicals Regulation and Standards. World-class scientific know-how in the use of NAMs for toxicity testing and other new risk assessment technologies such as physiologically based kinetic (PBK) modelling and biomonitoring, would help assess the safety of PFAS but indeed for application to any other new chemicals arriving into the market. This will require significant new investment but result in the development of highly trained scientific and technical specialists in chemicals regulation for all chemicals not just PFAS, supporting innovation at the same time as ensuring human health and environmental protection using sound science.

8. A regulatory framework for PFAS – what form could it take?

It is not effective to assess the safety of the thousands of PFAS in use today or those which could be in use in the future with current techniques. It would be too costly, too resource intensive and use too many

animals in testing. Therefore, to direct risk assessment in the most useful, efficient, timely and relevant way there needs to be (i) criteria for prioritising those substances that require a full scientific safety evaluation and (ii) a pragmatic way of performing a risk assessment for a single PFAS or ideally for a PFAS that is defined as representative of a group/category of PFAS. Banning all PFAS on persistence alone would take little scientific resource but could have massive unintended consequences for society with loss of important products and disruption of vital processes. The level of societal backlash to a regulatory policy based on persistence alone could be too high to make progress. Similarly doing nothing, when we have good evidence of the toxicity of some PFAS[6], is not an option as we must protect public health and environmental species.

A framework based on a multi-step 'traffic-light' decision-tree approach around PFAS use in society and on the basis of safety risk and impact assessments may be useful for regulatory action. We propose a green, amber, and red list approach (as depicted in Figure 2), to take appropriate regulatory action based on a defined level of acceptable risk according to an agreed set of criteria, as defined by the regulator working with science advisory mechanisms within government. This approach is designed to be proportionate, iterative, and agile, to ensure it accounts for evolving scientific evidence on PFAS.

Step 1 – Defining the chemical to be assessed – Is it a PFAS?

The framework starts by ascertaining whether the chemical(s) concerned is a PFAS, based on the OECD (2021) definition[7]. If the chemical concerned is not a PFAS, it is outside of the scope of this framework. If the chemical concerned is a PFAS, it then becomes important to distinguish whether the PFAS is used in a controlled way in a manufacturing process or is present in an end product.

Step 2 – Is the PFAS present in a manufacturing process or an end product?

PFAS chemicals are not only constituents in a diversity of products that people use on a daily basis but can also be used as an important precursor or aid in the manufacturing of other products, such as being used inside electronic devices, as lubricants for heavy machinery, or durable coating on equipment. The highly stable nature of PFAS means they are extremely useful in manufacturing processes and exposure to workers and environment could be near zero in a managed process. The generation of PFAS-containing waste would also need to be regulated by the manufacturer. Intermediate PFAS containing materials that are transient and not present in the end-product, could be treated as being part of a controlled manufacturing process. In the case where PFAS is used both in the manufacturing process and in the end-product, the conditions pertaining to both needs would need to be satisfied.

Step 3a – If the PFAS is used in the manufacturing process – can its environmental release be strictly controlled?

Many industrial processes involve the use of hazardous chemicals in the manufacturing process. However, these pose little or no risk to the environment and human heath because of effective containment and risk management practices. PFAS chemicals should be treated as safe, if used strictly in a manufacturing process where its occupational and environmental release can be controlled over the entire life cycle of the product, including its disposal. These PFAS could in principle be part of *Green List A, where their use is permitted under strict containment measures, within the approved manufacturing settings*. The PFAS can be used with occupational risk management measures in place, to protect worker health, and limited to a particular tonnage threshold. This would need to be monitored to ensure compliance.

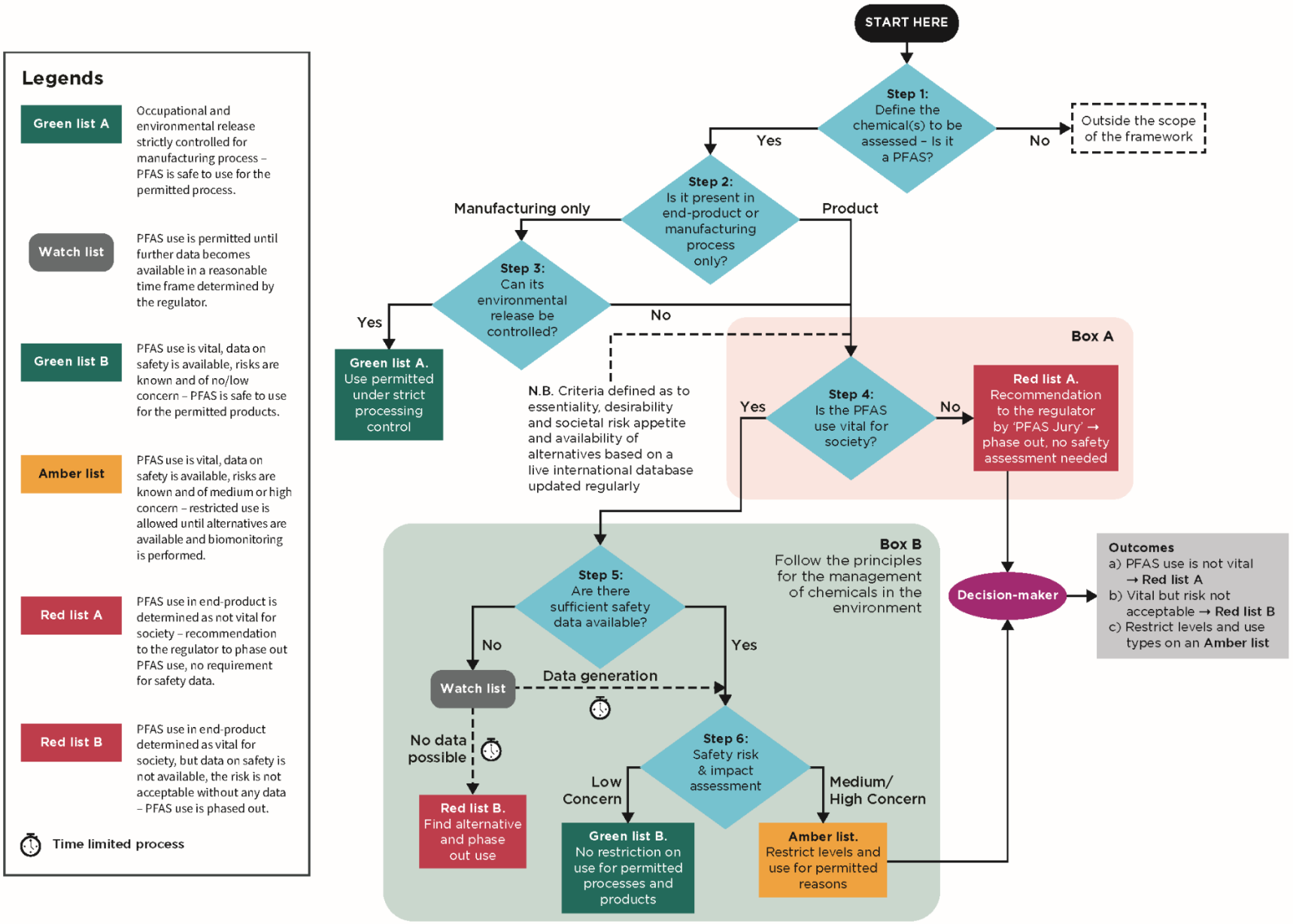


Figure 2: *A proposed risk-based framework based on a decision-tree approach around PFAS use and scientific evidence*

This situation does not put an obligation on the manufacturer to generate safety data for the PFAS being used solely in the approved manufacturing process to generate a non-PFAS containing product, but based on evidence of persistence there is an obligation to have data to show minimal PFAS exposure to workers and minimal PFAS release to the environment. A suitable emission policy would need to be enforced rigorously in case accidental pollution occurred, of what could be a PFAS of unknown toxicity.

If, however, the environmental and occupational release of the PFAS cannot be strictly controlled during the manufacturing process, and/or the PFAS remains present in the end-product, then the PFAS should be regulated based on the branch of the framework concerning PFAS use in an end-product.

Step 3b – Is the PFAS present in the end-product or is its release uncontainable in a manufacturing setting?

Many PFAS chemicals are present in products to which the public and consumers are exposed without any protections. Indeed, PFAS containing food, drinking water and medicines are ingested, and cosmetics, clothes and medical devices are in contact with the skin. Routes for any PFAS inhalation are poorly understood.

Exposure assessment and how to do it needs to be considered in this pathway. The question remains about whether chronic low exposures lead to bioaccumulation of PFAS in humans and wildlife over a lifetime. We know that PFAS can be measured in human blood and in animals, but are they causing adverse health effects from general exposure sources? This is a large uncertainty and where there are significant data gaps. Assessing all PFAS would take too long, therefore pragmatic approaches based upon reasonable assumptions will need to be developed.

In addition, there are many products used in the market, such as smart phones and other electronics, where the PFAS is safely isolated from direct exposure to the skin and environment. If in such cases, the environmental exposure of the PFAS is controlled throughout the life cycle of the product, including its reuse, recycling or disposal, the importance of such a product to our daily lives may justify its continued safe and sustainable use.

It is a significant ask to generate scientific evidence for every PFAS in every product type and so some triage is necessary to focus scientific effort and resources onto situations that require urgent action according to risk. Potentially new ways of evaluating risk are needed in a first tier of risk analysis. At this stage, before extensive and time-consuming resources are committed to exploring the scientific evidence, we ask if the product and the PFAS use is vital to society.

Step 4 – Is the PFAS vital for society?

Defining which PFAS use is vital for society should be a choice taken by citizens and governments and should be informed by the scientific and socio-economic evidence. This is best done in a transparent way to ensure all stakeholders know the rationale of why a decision has been taken. This process is represented by the **Box A** in Figure 2.

We advocate the establishment of a '*PFAS Jury*' where policymakers and members of wider society, review the advice presented by independent technical experts and sociologists/socio-economists, and this multistakeholder 'Jury' takes the ultimate decisions on which PFAS products and applications are vital for the future functioning of society and its prosperity. The realistic risks to environment and health must be

considered as paramount, but also in the context of the economic impacts of various options as to what could happen if an application or product was discontinued. A *'PFAS Jury'* would be a new concept, and could be established by the government including representatives of wider society, including civil society, industry, scientists and others, and they would be given the remit of making informed decisions on which PFAS and products needed to be evaluated in full for their safety and risk management, because they were deemed as 'vital' or 'highly desirable'.

The term 'essential use' is being discussed in legal terms in the EU for deciding whether PFAS are important for society, but there are different ways to look at 'essentiality': (a) the product as a whole is necessary for the health and safety or critical functioning of society – 'essentiality' as defined in the Montreal Protocol[16], and (b) the constituent PFAS chemical(s) concerned has no suitable and safe alternatives at this point in time. A product or PFAS may not be 'essential', but 'highly desirable' for society and a low risk may be considered an 'acceptable risk' that the wider public, appropriately informed, wishes to take. Being appropriately informed may include explicit product labelling when a PFAS is contained within a product, for example. Transparency in terms of a PFAS hazard profile would be necessary.

A 'PFAS Jury' should also take into account the availability of any suitable and safe alternatives that could reasonably replace the PFAS used in the product, even if functional performance was reduced. The suitability of the alternatives should take into account the unique physical properties conferred by the PFAS chemical for the proper functioning of the product (such as the thermal stability, repellency, breathability, etc.), as well as socio-economic analysis that makes the PFAS use highly desirable or irreplaceably vital. This process should involve all relevant stakeholders, including diverse and inclusive representation of the general public, together with experienced high calibre scientists as key contributors to decision-making. Ultimately it is a decision for the government about whether use of a safer but less functionally effective alternative should be mandated to replace PFAS, if one exists.

Is the PFAS vital for society?

Answer – No: If the products are not judged to be important and vital to society, then the significant resources that are required to assess safety could be disproportionate to a lack of benefits. In such circumstances, in this model, **the recommendation would be to stop use of a PFAS if risk outweighs benefit**, as part of *Red List A,* where their use should be phased out immediately. This should not be decided just by scientists, and we recommend that it would require a societal framework to make such decisions, led by government and a range of stakeholders, including scientific experts.

Answer – Yes: Industry and/or government scientists perform a scientific evaluation, generating data and performing a human health and environmental risk assessment.

Step 5 – Are safety data available for the vital PFAS or other relevant analogue PFAS'?

Once the PFAS use (or indeed a group of PFAS) has been established as vital, safety data review and evaluation can then be performed and the risks and impacts on health and environment assessed. This process should be carried out by a regulatory authority supported by knowledgeable scientists. Where safety data on the PFAS is not available but could in principle be generated, the PFAS could possibly be used with restrictions as part of a time-limited *Watch List*, where the use of the PFAS is permitted until further data becomes available in a reasonable time frame determined by the regulator. Environmental and biomonitoring should be carried out during this period.

The time limited nature of the *Watch List* means that the incentive to generate the data falls on the body/industry most likely to benefit from the longer-term use of the PFAS. This body could at Step 5 decide that the investment necessary for data generation does not justify the use of the PFAS concerned, and therefore allow the Watch-list period to lapse, no data are generated and the product to be phased out as part of *Red List B*.

If the unknowns or risks associated from continued use of a PFAS with no data on safety is considered too high, at the end of the time limit the PFAS should automatically be listed in *Red List B* – meaning their use needs to be phased-out within a predetermined period and an alternative substance used in its place; environmental and biomonitoring should be carried out by the respective competent authority to monitor presence over years.

The Watch List approach and Red List B addresses the overwhelming data gaps that are present for many PFAS in the market today and applies a precautionary principle for PFAS that lack available safety data.

Step 6 – Safety risk and impact assessment - What does the safety and socio-economic data say?

The available safety data would then be assessed by the regulatory body to conduct safety risk assessment and a given use of PFAS, with specific exposure considerations, determined to be either of low concern or medium/high concern. The PFAS of low concern can then be used for the specified purpose as part of *Green List B*, because the PFAS used in the product has been deemed vital for society as well. Certain conditions for continued use of the PFAS could be applied at this stage.

The PFAS with medium/high risk should be included in an *Amber List*, meaning their use is permitted only for the vital applications determined by the '*PFAS Jury*' and impact assessments need to be carried out. Stricter restrictions on its exposure to humans and the environment would need to be in place, while frequent environmental and biomonitoring should be carried out by the respective competent authority. There may need to be an aspect of 'the polluter pays' principle to enable this to happen. The *Amber List* should also act as a list to prioritise scientific research into possible further evidence gathering e.g., on toxic effects and environmental impacts, as well as remediation of legacy PFAS exposure and innovation in search of safer alternatives. Any PFAS in the *Amber List* should be immediately replaced when a safe and suitable alternative emerges, and the PFAS transferred into the *Red List B* in Step 5.

Steps 5 and 6 are represented in **Box B**, and we advocate using the principles for the management of chemicals in the environment, as detailed in the section below to define criteria for risk management.

Some important points of consideration

- **The positioning of societal importance of PFAS could occur in 2 places** in this framework. The considerations represented in Box A, where a multi-stakeholder '*PFAS Jury*' including citizens, as informed by the industry and scientific and socio-economic evidence, could also be placed following Step 5 and 6, succeeding the outcome of a scientific evaluation and where the known risk to health or environment is moderate or high. This latter placement of an evaluation of societal importance in the event that no scientific data were available, could mean substantial time and resources could be spent on data collection and analysis, and risk and impact assessments of substances, which may not later be deemed as vital for society anyway. In the positioning of Box A at the beginning of the process, significant resources can be focused on those PFAS that are most important to keep in use in society.

- **Scientists inform the decision-maker; scientists do not take the decisions.** The decision-maker in the UK setting is likely to be a government representative/agency with regulatory powers or a government Minister. The UK can take a responsible leading role but PFAS pollution cannot fully be tackled in the UK alone and scientists collaborate across boundaries. PFAS pollution is a global problem, one that requires global cooperation and collaboration to make the step-change in improvement that is needed at global level.

- **Current UK/EU REACH regulations do not mandate toxicological safety data to be provided for a PFAS when it is manufactured, imported, or used at <1tpa.** This means that for many PFAS there are no hazard characterisation data. Consideration needs to be given as to whether this situation is fit for purpose for highly persistent and functionally interchangeable substances such as PFAS. At least some basic hazard information should be mandated even at less than 1tpa; this could be in the form of *in silico/in vitro* hazard evaluation data, and ideally attempts made to place PFAS into groups based on predicted hazards. This would also be the case for alternatives with the same persistent properties.

- **Care should be taken in banning PFAS without understanding the alternatives** (which also may be manufactured at <1tpa) to avoid unintended and potentially worse consequences from the use of other more harmful or equally persistent substances. There should be a continuous review of the alternatives used to quickly identify new evidence on safety.

- **It is important to revisit the criteria of vital use, green and amber lists** at reasonable periods of time to take into account emergence of any safety data on PFAS or its alternatives that may alter safety risk assessments.

- **It would be useful to establish a global database of potential PFAS alternatives**. Reassessments should consider innovations in material sciences and the availability of alternatives periodically. Such a database should be continuously updated to scan for the emergence of substitutions from academia or material research facilities in the public and private sector, globally.

- **The safety and risk assessment process is resource intensive and needs to be performed by competent scientists**. It may be more cost-effective to prioritise safety risk assessment on PFAS that are deemed to be highly desirable and vital, rather than performing risk assessments on thousands of different PFAS only to then decide that their use is not strictly necessary or there exists a suitable alternative that can easily replace its use. It is with that view in mind that we suggest the PFAS put forward for full safety data and risk assessment be pre-determined by the '*PFAS Jury*'.

- **The decision on PFAS use should involve all relevant stakeholders** and is a decision better taken by the government of the day as representatives of the people. This is to ensure all aspects necessary to judge the vital nature of a PFAS use are considered. This is partly a socio-philosophical and ethical question which may not be within the current remit/expertise of the regulatory authority tasked with safety and technical data assessment.

This framework approach is accessible to non-scientists to the point of performing a risk assessment and implementing the findings. Although scientists are not the decision-makers, there are well established principles for the management of chemicals in the environment that may be useful to implement here.

9. Principles for the Management of Chemicals in the Environment

In our document, Principles for the Management of Chemicals in the Environment, we set out a package of complementary principles that would lead to pragmatic and proportionate decision-making for all chemicals.

A proportionate outcome from PFAS regulation can be achieved, whilst always putting people, the environment and best science at the heart of decision-making – considering the principles from the 1992 Rio Declaration on Environment and Development[17], of which the UK is a signatory – to assure a safe and sustainable outcome for all innovations and for our diverse populations of human beings and wildlife. We believe that when implemented as an interconnected set, the principles in our document Principles for the Management of Chemicals in the Environment working together can provide a sound foundation for flexible and agile regulatory decisions on PFAS that support innovation, whilst at the same time protecting health and the environment (Table 2). The consequence from having to consider the dimensions of all these principles can lead to an agile and proportionate outcome by those who grow used to working with them.

Table 2: *Principles for the management of chemicals in the environment and potential context for PFAS regulations*

Principle	Potential Context for PFAS regulation and future use
1. Integration principle (Rio Principle 4)	Ensure all decisions on PFAS relevant policy consider the potential for adverse environment and health outcomes, and that decisions improve the environment rather than make it worse
2. Sustainability principle (Rio Principle 3)	Ensure that inaction and decisions do not adversely affect the next generation
3. Global partnership principle (Rio Principle 7)	Given the persistent nature of PFAS in water and the fact they can be used, and pollution generated anywhere in the world, yet disperse in waters, collaborate globally to address the issue. Develop a live global list of alternatives to enable industry to replace PFAS in their products with safer and innovative alternatives.
4. Capacity building principle (Rio Principle 9)	Help those countries who are less well-regulated to understand the issues, build capability to improve the global outlook on PFAS pollution
5. Precautionary principle (Rio Principle 15)	Identify the risks and uncertainties and scientific data gaps. Take a precautionary starting position and proportionate regulatory action, with a view to generating more data to reduce uncertainty.
6. Risk & impact principle (Rio Principle 17)	Perform a risk and impact assessment as data allow
7. Mutual recognition principle	Understand the views of other countries and trading partners on the issue
8. Innovation principle	Look for innovative alternatives to PFAS or innovative solutions to managing their use to prevent harm
9. Citizens' 'Right to Know' principle	Inform and consult with citizens as to the proposed actions for PFAS management
10. Pollution prevention principle	Prevent any possible incidence of pollution by manufacturers

11. Polluter pays principle (Rio Principle 16)	If pollution happens by accident, the polluter pays heavily for the damage done
12. Rectification at source principle	Rectify the issue with the manufacturer/users/waste generators.
13. Impacts on other region principle (Rio Principle 12)	Do not ship PFAS or PFAS waste to harm other parts of the world. Understand the supply chains.

10. The need for simplified, connected, and consolidated regulatory action in the UK

PFAS are used in a range of products and applications, that cut across the regulatory purview of several UK government agencies. Manufacture of PFAS as raw materials, is currently limited to two UK companies; there are others worldwide. Many product manufacturers use PFAS, either in a process or as a constituent of a final consumer product.

The UK's responsibilities for chemicals regulation are spread across departments and regulatory bodies such as the Department for Environment Food and Rural Affairs (Defra), Business, Energy and Industrial Strategy (BEIS), Department of Health and Social Care (DoHSC), Health & Safety Executive (HSE), Environment Agency (EA), Foods Standards Agency (FSA), UK Health Security Agency (UK HSA, formerly PHE), and the agencies of the devolved nations in Scotland and Wales. Laws are enforced by local authorities' trading standards. Northern Ireland must follow EU laws as part of the Northern Ireland protocol following UK exit from the EU. The manufacture and import of PFAS in Great Britain (GB) fall under UK REACH regulation. Myriad product regulations including construction products, electronics, cosmetics, home improvement goods fall under the remit of the new Office for Product Safety & Standards (OPSS), foods within the Foods Standards Agency (FSA), and medicines under the Medicines and Healthcare Regulatory Agency (MHRA). Regulation involves complex network of stakeholders.

Products containing PFAS chemicals and environmental release from factories and via waste streams are managed and enforced by different and unconnected government agencies, and by the devolved national authorities. The need for chemicals sciences data and the skills in different government bodies varies accordingly. This fragmentation can make it challenging to work on a coordinated chemicals management plan for a broad class of chemicals such as PFAS and to arrive at consistent conclusions on any chemical where there are multiple sources of exposure.

It is the view of the RSC that PFAS should be regulated in the short term within UK REACH for known substances of concern but ultimately using specific new regulation as supported by a regulatory framework and accompanying technical guidance. Currently in England & Wales, the environmental aspects of PFAS exposure have been given priority and are actively being looked at under the UK REACH restriction programme with respect to environmental protection by the Environment Agency (England & Wales) working together with the Health & Safety Executive and Defra policymakers.

The UK has a strong regulatory base on which to build but its actors and experts are often disconnected. It is important that the UK maintains and invests in a strong scientific base for chemicals regulation. Due to the disparate responsibilities for chemicals regulation following EU exit, the UK now needs **a consolidated UK Chemicals Standards Agency**. Branded as such, this could in principle be a virtual umbrella body that pulls the expertise, know-how and consistency of policymaking under one consolidated and well-connected network for chemicals policy. PFAS regulation could be one of the first cases where the benefits and strength of such a body in forming risk-based regulation can be demonstrated across the piece.

In practice, a **UK Chemicals Standards Agency could turn the current fragmentation of chemicals regulation across departments into a strength** – by bringing more effective connectivity without massive structural change but with a new sense of visible authority and collective responsibility. PFAS regulation is a perfect example for this – they are chemicals that are used everywhere and there are perspectives from a range of government departments, but the dots are not well-connected and there is limited central coordination. If a UK Chemicals Standards Agency could have overarching responsibilities and powers to convene all of the departmental players together, then it is possible that a consistent approach to risk-based regulation for PFAS could be developed. This will rely on world-class scientific expertise and global collaborations with those interested in taking appropriate action on PFAS. Ideally such skills and expertise should be fostered within a research hub aligned to the needs of a chemicals agency and dedicated to developing the science required to underpin effective regulation.

11. Regulation as part of a global chemical strategy for PFAS

In our previous work '[A chemicals strategy for a sustainable chemicals revolution]', we indicated four strategic pillars that are important to consider when developing chemicals policy: Education, Regulation, Innovation and Circular Economy. This policy position predominantly discusses the *regulation* pillar for PFAS, but all four pillars are relevant to ensure improvements in PFAS pollution are realised.

Applying a chemical strategy approach to PFAS

Education – increase consumer awareness of PFAS uses, importance to society, hazards and risks and transparency of decisions taken and law implemented. Incorporate awareness on the PFAS issues in further education programmes. Share knowledge globally and build worldwide capability through UN forums.

Regulation – design frameworks based on science and societal impacts, that lead to workable legislation to achieve an outcome that keeps us safe whilst enabling innovation that benefits society [*this position paper*].

Innovation – development of technologies and processes that better control PFAS exposure to humans and environment; developing safer alternatives to PFAS with the same functional benefits. Innovation in methods to assure safety.

Circular Economy – challenging for persistent and toxic PFAS, unless exposure can be completely controlled; data on supply chains of PFAS use; considering safe and sustainable end of life solutions, and life cycle analysis considerations, e.g., ultimate incineration of PFAS wastes in cement kilns.

The starting position in this paper, based on the evidence today and given the many unknowns and data gaps, is that PFAS manufacture and use must be regulated to ensure relevant data are generated to ensure continued safe use. The question is what type of regulatory framework is most effective to promote effective UK and also global action. Many regulatory authorities in the world support risk assessment and risk management of chemicals as a pragmatic, protective and effective basis of regulation. We advocate the use of a societally acceptable, risk-based regulatory framework, using state-of-the-art scientific evidence integration to support pragmatic and effective decision-making for PFAS.

Given that PFAS pollution of water knows no boundaries, we advocate for global collaboration on PFAS policy, and hope that bodies such as UNEP, UN SAICM, OECD, ECHA, US EPA and associated science-policy interfaces can foster such collaboration. [The RSC has called for an independent intergovernmental panel for chemicals and waste to be established] at UN level on a par with the IPCC and IPBES, and it is expected that given PFAS use is such an important global issue it should be given a priority in such a knowledge sharing and horizon scanning forum. Effective regulation is a key pillar of reducing PFAS pollution, but not the only pillar. Further work is needed globally on education, innovation, and circular economy aspects.

12. Concluding Remarks

The Royal Society of Chemistry includes members and stakeholders across academia, government, charities, NGOs, and the private sector. Guided by the best scientific evidence and expertise in the chemical sciences, the RSC can play a crucial convener role in the ongoing discussion on how to best manage PFAS. New and targeted science is needed to support decision-makers to in taking effective action that reduces PFAS pollution and ensures public safety and environmental protection.

We call on all governments to take certain actions that would support progress on PFAS:

- Focus dedicated regulatory resources to regulate all PFAS uses via risk-based evaluations informed by scientific evidence
- Call via the UN for the establishment of a new intergovernmental panel for chemicals pollution – where PFAS science, evidence and risk assessment should be an early topic of knowledge sharing.
- Call for a continually updated, global authoritative database to be established on PFAS alternatives

In the UK, we call on the government to:

- Consider establishing a credible and authoritative multi-stakeholder 'PFAS jury' to decide for the UK which PFAS are 'vital' or 'highly desirable' for the benefit of future society
- Establish a UK Chemicals Standards Agency – an umbrella body that connects all relevant agency actors for which chemicals safety is an important topic
- Invest in a new world-class applied research hub for chemicals policy – including research on the science to support and advance PFAS regulation, to support global collaboration.

Contact

The Royal Society of Chemistry would be happy to discuss any of the issues raised in our statement in more detail. Any questions should be directed to the RSC Policy & Evidence Team at [redacted]@rsc.org.

This document was prepared by Camilla Alexander-White and Oishik Banerji (RSC Policy & Evidence Team) with support from Louise Oldham and Hannah MacDonald, and following RSC engagement events in 2020-2021 with the RSC expert member community, members of the RSC Environment & Regulation Collective and involving members of the international scientific community. Special thanks to Dr David Megson (Manchester Metropolitan University) for working with the RSC and chairing these events.

About us

With about 45,000 members in over 100 countries and a knowledge business that spans the globe, the Royal Society of Chemistry is the UK's professional body for chemical scientists, supporting and representing our members and bringing together chemical scientists from all over the world. Our members include those working in large multinational companies and small to medium enterprises, researchers and students in universities, teachers, and regulators.

Abbreviations

BEIS	Department for Business, Energy and Industrial Strategy
Defra	Department for Environment, Food and Rural Affairs
DoHSC	Department of Health and Social Care
EA	Environment Agency (England & Wales)
ECHA	European Chemicals Agency
EPA	Environment Protection Agency
EU	European Union
FSA	Food Standards Agency
GB	Great Britain – comprising of England, Scotland, and Wales
HSE	Health and Safety Executive
IPBES	Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services
IPCC	Intergovernmental Panel on Climate Change
MHRA	Medicines and Healthcare products Regulatory Agency
NHANES	National Health and Nutrition Examination Survey
OECD	Organisation for Economic Co-operation and Development
PBPK	Physiological based pharmacokinetic modelling and simulation
PFAS	Per- and poly-fluoroalkyl substances
PHE	Public Health England, replaced by UKHSA since April 2021
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RSC	Royal Society of Chemistry
SAICM	Strategic approach to international chemicals management
SETAC	Society of Environmental Toxicology and Chemistry
UK	United Kingdom
UKHSA	UK Health Security Agency
UNEP	United Nations Environment Programme
US	United States

References

[1] Glüge, J. et. al. An overview of the uses of per- and polyfluoroalkyl substances (PFAS). Environ. Sci.: Processes Impacts, 2020, 22, 2345-2373. https://doi.org/10.1039/D0EM00291G

[2] Environment Agency. Perfluorooctane sulfonate (PFOS) and related substances: sources, pathways and environmental data, 2019. https://consult.environment-agency.gov.uk/environment-and-business/challenges-and-choices/user_uploads/perfluorooctane-sulfonate-and-related-substances-pressure-rbmp-2021.pdf [Accessed 28 June 2021]

[3] Guo, R., et al. 2016. Application of a comprehensive extraction technique for the determination of poly- and perfluoroalkyl substances (PFASs) in Great Lakes Region sediments. Chemosphere 164, pp 535-546, https://doi.org/10.1016/j.chemosphere.2016.08.126.

[4] Sunderland EM, Hu X, Dassuncao C, Tokranov AK, Wagner CC, Allen JG. 2019. A review of the pathways of human exposure to poly- and perfluoroalkyl substances (PFASs) and present understanding of health effects. *J Expo Sci Environ Epidemiol* 29:131–147

[5] ATSDR. Toxicological Profile for Perfluoroalkyls, 2021, 1.6, 1-993. https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf [Accessed 28 June 2021]

[6] Environment Agency – Poly- and perfluoroalkyl substances (PFAS): sources, pathways and environmental data: summary – research and analysis https://www.gov.uk/government/publications/poly-and-perfluoroalkyl-substances-pfas-sources-pathways-and-environmental-data/poly-and-perfluoroalkyl-substances-pfas-sources-pathways-and-environmental-data-summary Published 26 August 2021 [Accessed 22 September 2021]

[7] OECD (2021), Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD Series on Risk Management, No. 61, OECD Publishing, Paris.

[8] Cousins, I. T., et al. Strategies for grouping per- and polyfluoroalkyl substances (PFAS) to protect human and environmental health. Environ. Sci.: Processes Impacts, 2020,22, 1444-1460 https://doi.org/10.1039/D0EM00147C

[9] Campbell, J., Allen, B., Olsen, G., Elcombe, C., Doyle, E., Evans, J., Clewell, H., 2016. Evaluation of the short-term clearance of perflourooctanoic acid (PFOA) in a clinical trial using a PBPK model and Markov chain Monte Carlo analysis. In: Poster at the Society of Toxicology Annual Meeting.

[10] Xu, Y., Fletcher, T., Pineda, D., Lindh, C.H., Nilsson, C., Glynn, A., Vogs, C., Norstr¨om, K., Lilja, K., Jakobsson, K., Li, Y., 2020. Serum half-lives for short- and long-chain perfluoroalkyl acids after ceasing exposure from drinking water contaminated by firefighting foam. Environ. Health Perspect. 28, 7. https://doi.org/10.1289/ EHP6785. CID: 077004.

[11] Dourson, M., Gadagbui, B., 2021. The Dilemma of perfluorooctanoate (PFOA) human half-life. Regulatory Toxicology and Pharmacology 126 (2021) 105025 https://doi.org/10.1016/j.yrtph.2021.105025

[12] Graber JM, Alexander C, Laumbach RJ, Black K, Strickland PO, Georgopoulos PG, Marshall EG, Shendell DG, Alderson D, Mi Z, Mascari M, Weisel CP. Per and polyfluoroalkyl substances (PFAS) blood levels after contamination of a community water supply and comparison with 2013-2014 NHANES. J Expo Sci Environ Epidemiol. 2019 Mar;29(2):172-182. doi: 10.1038/s41370-018-0096-z. Epub 2018 Nov 27. PMID: 30482936; PMCID: PMC6380951.

[13] https://www.congress.gov/bill/117th-congress/house-bill/2467/text [Accessed 30 September 2021]

[14] Grulke, Chris, G. Patlewicz, B. Meyer, A. Williams, AND A. Richard. Structure-based categorization of Per- & Polyfluoroalkyl substances in the DSSTox database and EPA's ToxCast inventory using Markush representations. Presented at American Chemical Society Spring Meeting, Orlando, FL, March 31 - April 04, 2019. https://doi.org/10.23645/epacomptox.8022443

[15] Lougee, R., G. Patlewicz, Chris Grulke, A. Williams, C. Yany, J. Rathman, T. Magdziarz, AND A. Richard. PFAS Toxprints: A Hierarchical Structure-Based Categorization Method for Characterization of Per- and Polyfluoroalkyl Substances. American Chemical Society Fall 2020 Meeting (Virtual), San Francisco, California, August 16 - 20, 2020. https://doi.org/10.23645/epacomptox.12834329

[16] The concept of essential uses was first applied under the Montreal Protocol on Substances that Deplete the Ozone Layer (the "Montreal Protocol on Substances that Deplete the Ozone Layer" (1987) https://ozone.unep.org/treaties/montreal-protocol/montreal-protocol-substances-deplete-ozone-layer) [Accessed 15 November 2021]

[17] 1992 Rio Declaration on Environment and Development - https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A_CONF.151_26_Vol.I_Declaration.pdf [Accessed 14 September 2021]

ROYAL SOCIETY OF CHEMISTRY

When the science is uncertain, what is the role of risk-based approaches and precautionary control in chemicals policy?

9 June 2022, Royal Society of Chemistry, Burlington House, London, UK

Workshop report

Contents

This document is a report of a science-policy workshop attended by around 60 delegates, bringing natural scientists, social scientists and policymakers together to discuss risk and precaution in chemicals policy and chemicals safety decision-making. This report does not contain any recommendations and it does not represent the views of any of the organising committee or the organisations which they represent. The content of the presentations given at the event is reflected, and the general nature of the discussions that arose is presented, with points raised in the breakout groups gathered as themes at the end of the document. It is the intention that these perspectives can feed into future discussions on the evolution of chemicals policy, particularly in areas where the science is currently uncertain.

Introduction

Chemicals policy in the UK today is based mainly on a combination of regulatory regimes and industry self-management and due diligence. To release chemicals and products into the market or into the environment without any knowledge on exposure and hazards is highly risky; we know some chemicals are hazardous to human and environmental health, and not all hazards can be predicted. We also know from the Lancet Commission reports that human health is being adversely affected by poor air quality and pollution.[1] With global chemicals production set to double by 2030, pollution must not double.[2] Human health and the environment could be even more severely harmed if the pace of innovation outstrips safety data generation and the implementation of effective chemicals management strategies. Conversely, to ask for a comprehensive traditional exposure assessment and toxicology testing programme covering the many multiple possible effects for hundreds of substances can cost millions of pounds, take many years and be a barrier to innovation.

Regulation is most effective when it is proportionate and drives innovation and diligent practices, to reduce, and ideally minimise, the harms of hazardous chemicals on human health and the environment. As part of the discussions on a UK Chemical Strategy, the government needs to find pragmatic and proportionate ways forward in chemical risk management and decision-making that society can trust to keep them safe and whilst also enabling innovation. The process should incorporate sound scientific evidence as much as possible. Consideration should be given to using new approach methods (NAMs), new concepts, new risk paradigms, and combining natural sciences and social sciences into decision-making. We need innovation in regulatory risk assessment to support innovation in chemicals, whilst maintaining high levels of environmental and human health protection.

The use of risk-based regulation in the context of rapid innovation

Risk-based regulation acknowledges that while a chemical may be hazardous, the risk it poses can be reduced by controlling exposure to the chemical. This type of regulation requires scientific data to understand both the hazard and exposure of the chemical. In some cases, scientifically based conservative assumptions can be used in modelling. However, actual measured or modelled data is not always available, and the science is not always certain, such that regulatory decisions on whether to authorise or restrict use of a chemical must often be taken with provisos and in the face of significant uncertainty.

The chemicals industry is expected to double globally by 2030.[2] At this rapid pace of innovation and growth and given the current levels of resourcing and regulatory approaches, the scientific methods used to gather safety and exposure data for substances cannot be expected to keep pace. Recent evidence suggests that the 'planetary boundary' is already being exceeded by chemicals in the environment, i.e., our planet is struggling to cope with the overall anthropogenic chemical burdens in air, land and water and we will start to see more adverse effects in the years ahead.[3,4] Additionally, there are chemicals currently in use for which there is insufficient data available to fully evaluate their safety. The Royal Society of Chemistry has developed policy positions for two such areas where the pace of innovation has outstripped the generation of safety evidence, namely poly- and perfluoroalkyl substances (PFAS) and potential endocrine disrupting chemicals (EDCs).[5]

The precautionary principle and essential use criteria

The precautionary principle states that neither a lack of information nor scientific certainty should delay action or regulation when there are potential severe and irreversible consequences. This principle underpins why the concept of essential use has been proposed by some as a possible pragmatic risk management solution when faced with potentially large numbers of data-poor chemicals, for which a substance-by-substance approach to regulation can be slow and impractical. The essential use concept involves identifying the applications of chemicals and allowing their use when 'essential' but prohibiting other uses to limit exposure and potential harms. The concept was introduced in the Montreal Protocol, where a substance qualifies as 'essential' only if:

"1. it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and

2. there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health"[6]

The Montreal Protocol was narrow in scope, regulating select ozone depleting substances. If the essential use concept is to be applied to a wide-ranging group of data-poor substances, there are important methodological and practical questions to be further defined, such as

- which applications qualify a substance as 'essential,'
- when the concept should be applied,
- how it compares with other possible approaches to regulation,
- who makes these important decisions.

In the workshop 'When the science is uncertain, what is the role of risk-based approaches and precautionary control in chemicals policy?', around 60 attendees were brought together from academia, industry, NGOs, policy and professional bodies from the UK and EU to share and discuss this question.

The workshop was co-sponsored by the Royal Society of Chemistry (RSC), the Department for Environment, Food and Rural Affairs (Defra) and the Chemicals Industry Association (CIA). We invited the speakers below to set the scene, prior to an afternoon of breakout discussion groups on the practicalities of using risk-based regulation, precautionary control and the essential use concept to regulate chemicals when scientific evidence is uncertain.

Workshop details

The following persons are thanked for chairing and speaking during the workshop sessions.

Chairs:

- Professor Ragnar Lofsted (Kings College London)
- Catherine Gunby (Fidra)
- Silvia Segna (Chemicals Industry Assocation)

Introductory Speakers:

- Stavros Georgiou (Health & Safety Executive)
- Dr Camilla Alexander-White (Royal Society of Chemistry)
- Edward Latter (Defra)

Panellists:

- Geoffrey Podger (Kings College London)
- Professor Frederic Bouder (University of Stavanger)
- Professor Nick Pidgeon MBE (Cardiff University)
- Andrew Fasey (Mayer Brown)
- Professor Ian Cousins (Stockholm University)
- Dr Anna Watson (CHEM Trust)
- Dr Silke Gabbert (National Institute for Public Health and the Environment, Netherlands)
- Dallas O'Dell and Woong-Ki Lee (The London School of Economics and Political Sciences)

Workshop presentations

Risk and precaution

Opening the workshop, **Mr Geoffrey Podger** observed that the role of scientists is to present options to politicians. He warned that in some cases politicians "are very much welcoming of scientific advice, provided it agrees with what they've already decided to do". Therefore, he called for transparency and accountability, proposing that when publishing a decision, politicians also publish the scientific evidence it is based on, or the justification for why it is not based on scientific evidence. He also stressed the importance of defining terms such as 'hazard', 'risk' and 'essential' so that no one party can take advantage of them being unclear.

Mr Podger also voiced concerns around the diminished inclusion of science and evidence in EU decision-making in recent years, particularly as the UK develops its post-Brexit chemicals strategy following EU exit. Due to international trading, pressure will come from industry for new UK regulation to follow EU regulation. Mr Podger suggested that the EU Chemicals Strategy for Sustainability (CSS) will be largely determined by EU politicians, who are driven by their own political agendas, and that there would be opportunities for the UK to have science and risk-based regulation. However, he recognised this would lead to divergence between EU and UK regulatory regimes, which would bring challenges.

Professor Frederic Bouder's presentation explored how to define important terms. Professor Bouder noted that academics and governments usually define 'precaution' in similar terms: as something that is justified when there is a significant threat combined with high levels of scientific uncertainty. In practice however, precaution is applied to different situations across different countries and areas of regulation, some of them not meeting those conditions. Professor Bouder suggested that this disparity is often due to variations in the appreciation of risks and benefits and the levels of threat and uncertainty that are deemed acceptable by decision-makers. Quoting from a seminal paper on risk by Fischoff, Professor Bouder shared factors that affect the acceptability of risk:
"the certainty and severity of the risk; the reversibility of the health effect; the knowledge or familiarity of the risk; whether the risk is voluntarily accepted or involuntarily imposed; whether individuals are compensated for their exposure to the risk; the advantages of the activity; and the risks and advantages for any alternative".[7]

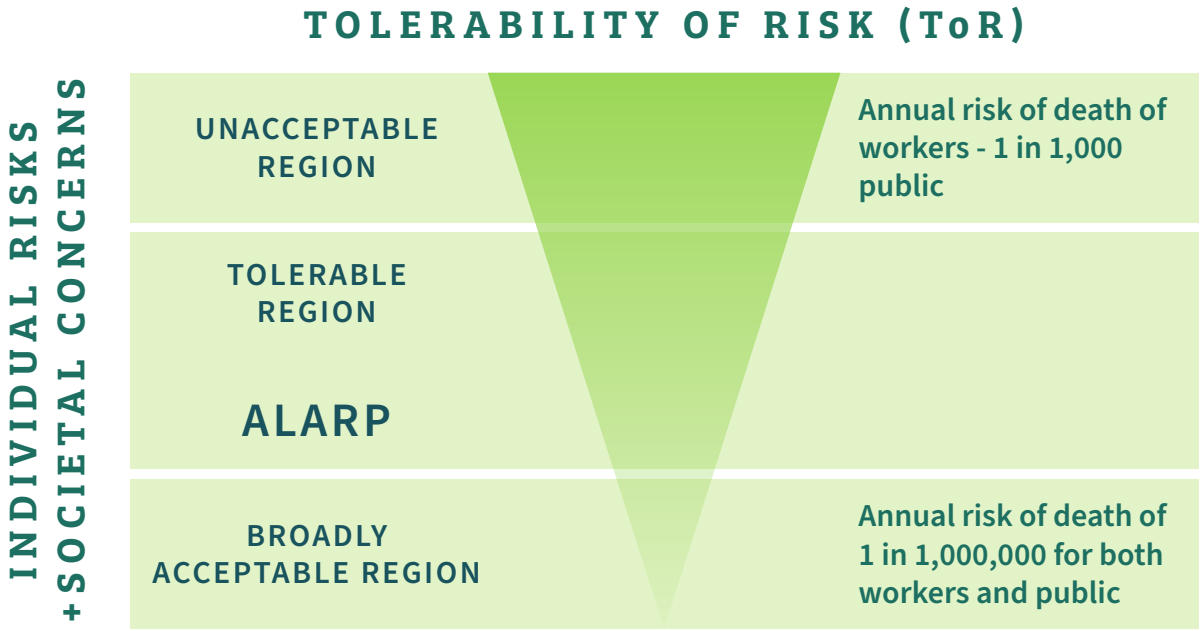


Figure 1: Tolerability of Risk diagram

The ToR diagram accounts for the effects of both individual risks and societal concerns on the acceptability and tolerability of risk. ToR is informed by death rates and surveys of the public. ALARP: as low as reasonably practicable. Diagram from Professor Frederic Bouder's presentation.

While the risks associated with certain substances can be defined as acceptable or unacceptable, there are some substances that have risks but are still considered as needed by society. This is where the tolerability of a risk is pertinent. Professor Bouder shared the Tolerability of Risk (ToR) diagram (figure 1), a decision aid for policymakers developed by the Health and Safety Executive (HSE) in Great Britain.[8,9] ToR considers both individual risks and societal concerns and categorises substances as unacceptable, tolerable and acceptable. Measures should be put in place to lower the risks of chemicals in the tolerable region. Professor Bouder suggested that an updated ToR diagram may help make risk communication around chemicals regulations clearer in the future.

The social factors affecting the acceptability of risk are not unique to chemicals regulation. Professor **Nick Pidgeon** shared lessons learnt from other risk areas such as climate change and biosecurity. The amount of communication about a risk has an impact on how the risk is perceived by the public. This was seen during the **social amplification of the 2012 Chalara outbreak**, where Chalara (ash tree dieback) quickly became a top priority for the UK Government after a rise in media coverage increased public awareness of the outbreak. Similarly, whether communication focuses on the costs or benefits of an issue will shape public perceptions.

Narratives, attitudes to risk and the values of the public also play a role in the acceptability of risk. During the **UK's Citizens Assembly on Climate Change**, participants overwhelmingly chose nature-based solutions for carbon removal, even though evidence suggests that nature-based solutions alone may not be sufficient to reach the UK's current carbon removal requirements. Additional social factors affecting the acceptability of risk are the trust the public has in experts and policymakers, and the distributional equity of a risk.

Professor Pidgeon also encouraged policymakers to be aware of the Collingridge dilemma, which is the idea that because of uncertainties risks cannot always be predicted before a technology has been fully developed, but once the technology is in use, it may be too late to avoid the risks.[10] To address the Collingridge dilemma, Professor Pidgeon suggested that initial deployment decisions should wherever possible be reversible, organisations should be flexible, and small-scale trials should be performed before full implementation.

Essential use within the context of risk management

A commitment to define criteria for the application of the essential use concept was included in the EU's **Chemicals Strategy for Sustainability** (CSS) under the new **EU Green Deal**. The CSS includes 85 actions and 12 proposed amendments to EU REACH and is intended to simplify and strengthen existing EU frameworks. Key actions include applying the essential use concept to phase out the most harmful chemicals, fast-tracking restrictions based on hazard, and emphasising essentiality and sustainability.

Mr Andrew Fasey highlighted stakeholder concerns about the incoming legislation. When essential use was used in the Montreal Protocol, the scope of chemicals was small, but the CSS will apply the concept on a much larger scale. Stakeholders are unsure how the essential use concept will effectively and efficiently regulate a broad range of chemicals. Additionally, Mr Fasey raised concerns that the amount of incoming EU legislation is overwhelming and that it is unclear how the parts will be integrated together and within the existing framework. The terms 'essential' and 'sustainable' have not yet been defined by the CSS. These issues make it difficult for stakeholders to understand how the CSS will affect them.

As deeming a chemical essential requires there to be no safer and economically feasible substitute, alternatives assessments will have to be carried out for many chemicals. These assessments are not simple, and stakeholders are concerned that the EU does not have the resources to carry out these assessments in a way that makes the essential use concept more efficient than existing risk- and hazard-based regulation. Mr Fasey suggested that the essential use concept should be used to make quick decisions about lots of chemicals, then companies can apply for exemptions retrospectively if they believe their use is essential.

Professor Ian Cousins, who has made significant contributions to current discussions in the UK and EU about the essential use concept, stated that risk assessment has failed for per- and poly-fluoroalkyl substances (PFAS). As more evidence has emerged about the hazards of PFAS, the environmental levels considered safe have decreased, but as PFAS are persistent and have already been in use, safe levels have already been exceeded. Professor Cousins also noted that it is impractical to completely ban all PFAS as some of their uses are considered essential in some critical areas of society, e.g. in medical devices and some occupational protective clothing.

Professor Cousins shared aspects to consider when applying the essential use concept. First, the substances for consideration need to be identified and the concept should only be applied to the 'most harmful substances' for which traditional risk assessment approaches may not be appropriate for their safe management. The essential use concept can be made more efficient by regulating chemicals as groups. Second, there are different ways the function of a chemical can be substituted. For example, Bisphenol-A (BPA) in thermal paper receipts can be substituted by a different chemical (chemical function), thermal paper receipts can be created using different materials (end use function), or electronic receipts can be used instead (service function). Third, to be 'essential' substances must be critical for the health and safety of society and have no acceptable substitutes. Professor Cousins shared that more clarity on what defines 'essential' will be available soon when the Wood Report, commissioned by the European Commission to define criteria for essentiality, is published.

Dr Anna Watson presented insights from the **UK Chemicals Stakeholder Forum's** working group on essential use. The purpose of the working group was to discuss how the essential use concept has been used in the past and is proposed to be used to regulate hazardous chemicals. The stakeholders viewed the essential use concept as a pragmatic way of reducing pollution and speeding up chemical regulation. They agreed that the application of the essential use concept should require some evidence of harm and prioritise the most hazardous chemicals. Stakeholders also argued that persistence alone also justified the application of the essential use concept. However, the stakeholders also had some concerns. First, not all the uses of chemicals are known and therefore it could be difficult to determine whether a substance is essential. Second, essential uses should improve quality of life, but measuring this impact varies on whether the benefit is individual or societal.

Public perception of essential use

Note that the following speakers presented results from pilot studies which should not be used to draw conclusions. Results from the main studies, once completed, will help to provide insight into public perceptions of essentiality and risk.

Dr Silke Gabbert presented her work at the Dutch National Institute for Public Health and the Environment. The study surveyed citizens of seven European countries on the essentiality of persistent chemicals. The pilot study has been completed and results from the main study are currently being analysed. Results from the pilot study suggest that perceptions of 'essential' and 'non-essential' differ depending on the country and use of the chemical. Dr Gabbert called for definitions of 'necessary,' 'critical for the functioning of society' and 'acceptable,' as well as inclusions of citizens' perspectives in decision-making.

Dallas O'Dell and **Woong-Ki Lee** presented their work on public perceptions of PFAS in the UK. The pilot study consisted of two parts: a needs-based assessment and an economics-based assessment.

The needs-based assessment evaluated perceptions of which products containing PFAS are essential for the critical functioning of society. Products were either functional (products with functional and technical capabilities) or experiential (products that people desire). The pilot results suggest that experiential products were perceived as less essential, needed, and worth consuming than functional products. Additionally, results suggested that PFAS added significantly lower benefit to experiential products compared to functional products.

In the economics-based assessment, participants were informed that the risks of PFAS are uncertain and that because PFAS is persistent the risks could be irreversible. Participants were asked how much of a price increase for everyday products they would be willing to accept in return for a ban of PFAS that would remove health and environmental risks entirely. Pilot results suggested that participants were willing to pay £25 per month on average, although this number was regarded by some as higher than expected and may not be representative of opinions of risk from chemicals more broadly.

Breakout sessions

To understand how risk assessment and precautionary control could be used to regulate data-poor chemicals, we asked participants to discuss four questions. The key points from these discussions are summarised below.[11]

Breakout one: risk and precaution

Question one: How could a risk-based approach effectively protect the environment and society from chemicals with insufficient data (or when the science is uncertain)?

- There are different types of uncertainty depending on what data is available. Therefore, whether a risk-based approach could provide effective protection differs on a case-by-case basis.
- Grouping allows data from representative chemicals to be used via the concept of read-across to efficiently regulate multiple similar chemicals for which data may be insufficient.
- REACH legislation has data requirements to deal with uncertainty. Issues arise from situations that were not considered when the legislation was made, such as mixtures and persistence without proven harm. Lessons must be learnt if there are evidenced cases where risk assessment has failed before.
- When regulating chemicals for which the science is uncertain there are factors to be considered:

1. Acceptability
   - The public's appetite for risk should be gauged.
   - The risk to workers differs from risk to the public.
   - The public has delegated authority to regulators to make decisions in their interest.

2. Transparency
   - Uncertainty is intrinsic to science.
   - Communication to the public should be done in a way that is understandable (e.g. likelihood of being struck by lightning).
   - Communication to the public should be done by scientists.
   - Policymakers are not required to follow scientific advice but must be transparent when they do not.
   - Transparency from industry makes more data available.

3. Flexibility
   - Legislation must be prepared to adapt to new scientific approaches and data.
   - A timescale is needed for review and revisions to regulations.

4. Prioritisation
   - A framework is needed for prioritising chemicals for further research.
   - Methods could include modelling, machine learning, toxicokinetics, New Approach Methods (NAMs).

Question two: Under what circumstances should precautionary control be applied?

- Precaution should be applied in the following circumstances:
  - when the science is uncertain in either the hazard assessment or exposure assessment, as defined by independent scientific experts
  - when a substance is chemically or functionally related to a group that is known or strongly suspected to be harmful
  - when the adverse effect may be irreversible
  - when the substance is persistent or bioaccumulative, as a toxic threshold will be reached at some point
  - when it is unclear how the chemical will be used, i.e., details of use are not provided and therefore exposure cannot be so easily controlled
  - when vulnerable populations come into contact with the substance
  - when the substance is produced in amounts over a certain tonnage
  - when the substance is used widely or has high environmental motility
- There is currently no regulatory pathway for a substance to move to a lower risk category if further evidence shows it to be less harmful than initially thought. Therefore, if precaution is being used to regulate chemicals, there must be a framework to lift precaution as more data becomes available.

Breakout two: essential use

Question three: How can the concept of essential use adequately deal with uncertain risk, and can it deliver a more effective and efficient approach to risk management of chemical groups? Why/why not? How could the essential use concept fit into existing regulatory regimes?

- The Montreal Protocol is regarded as a successful implementation of the essential use concept. It was effective because it was international, and exemptions were narrow and time restricted. The Montreal Protocol did result in some regrettable substitution as some alternatives turned out to be greenhouse gases that affect climate change.
- It is easier to regulate obviously essential and non-essential substances, but those in the grey area are difficult. Who decides which grey area substances are essential and how can you ensure consistency in this? A form of regulation that encourages business to shift away from all those uses that the business clearly accepts as non-essential (e.g. given cost-effective substitutes) could help narrow the list of substances which will require more effort to regulate effectively.
- Exposure still needs to be considered for substances deemed essential. Non-essential uses should not be penalised if exposure is already well controlled.
- Deeming a substance 'non-essential' incentivises R&D for safer alternatives. Conversely, deeming a substance 'essential' disincentivises R&D for safer alternatives.
- It is important to avoid regrettable substitution. Alternative substances must be assessed to ensure they are safer than the original, but this takes time. Alternatives may not be entirely safe, but just less harmful than the original.
- Introducing the essential use concept in one jurisdiction risks pushing industry into less regulated countries.
- It is difficult to know what all the uses of a chemical are, and therefore whether the chemical is essential. This would require significant time and effort and it is unclear whether the essential use concept would be more efficient than current methods used in regulation. There would have to be an onus on industry to prove the substance is essential.
- Enforcing the essential use concept would be difficult and require increased NGO monitoring for whistleblowing, especially considering the very large volume of different uses and competing views on whether each use is essential.

Question four: What are the alternatives to essential use and are they preferable? Why/why not? Could essential use be used in combination with existing/new approaches?

- Cost/risk-benefit analysis is preferable as it acknowledges the trade-offs in a transparent way and helps in understanding issues in an evidence-based manner. The essential use concept can be stricter than cost-benefit analysis as 'essential' and 'beneficial' are not the same.
- Risk assessment can be used but this requires data and knowhow and is regarded as expensive.
- New approach methods (NAMs) could allow data to be gathered more efficiently, allowing risk assessments to be performed. Implementation of NAMs would require regulatory transformation.
- Authorisation under REACH regulation makes the essential use concept redundant.
- It would be useful to be able to test-drive policy before full introduction

Recurring themes in presentations and breakouts

The following is a summary of the major themes that emerged from the workshop. These are not recommendations, but rather a starting point for further discussions about risk-based decision-making, precautionary control and the essential use concept, and important considerations for their application.

1. **Definitions** of relevant terms are needed so that it is clear what effect proposed regulations would have. Key terms include:
   - hazard
   - precaution
   - acceptable
   - uncertain
   - essential
   - sustainable
   - necessary
   - critical for the functioning of society
2. Apply the essential use concept as an **efficient means of applying precautionary control** for substances with limited toxicity and/or exposure data.
   - Finding out about the uses and possible substitutes of a chemical is time consuming. Instead, an authorisation system could be used for essential uses.
   - Uncertainty should not prevent action if there is some evidence of harm.
   - Regulate chemicals in groups to increase efficiency.
   - Transparency from industry will make regulation using the essential use concept more efficient.
3. **Regulation must be dynamic** to allow changes in regulation as more data becomes available, and to avoid regrettable substitution and the Collingridge dilemma.[12]
   - There must be a framework with a timeline to lift or increase precaution as more data becomes available.
   - Well established 'command and control' regulation restricting certain substances could potentially be complemented by a broader regulatory framework to multiply industry good practice and help move the market (e.g. compulsory company auditing or reporting of action to move away from chemicals of concern deemed non-essential by the company).
   - Alternative substances must be tested to make sure they are safer than the original and the outcome of these tests must be acted upon.
   - Reversible decisions, flexible organisations and small-scale trials reduce risk of the Collingridge dilemma.
4. Regulation should be based on **frameworks and evidence**.
   - Frameworks are needed to ensure consistent decision-making.
   - Essential use could be one part of a risk assessment framework.
   - A framework is needed for prioritising chemicals for further research.
   - Governments should publish the scientific evidence that regulatory decisions are based on.
   - Industry needs to be transparent about how its hazard data is used through the entire regulatory process, including the development and generation of new data to inform new regulations.
5. The **public's perspective** needs to be considered, and governments should **communicate** and be **transparent** to gain public trust.
   - Public consultations and participatory processes provide insight into public perceptions of essentiality and risk to inform regulatory decisions.
   - Regulators need to be aware that perceptions will change in different locations/ different groups and depending on how the issue is presented to them.
   - Frameworks that take acceptability into account (such as the Tolerability of Risk diagram) help to make risk communication clearer.

Other suggestions from participants:

- Exposure of essential chemicals still needs to be controlled.
- Non-essential uses should not be penalised in situations where exposure is well controlled.
- R&D for safer alternatives to essential chemicals should be incentivised.
- The essential use concept cannot resolve all issues of chemical pollution.
- The transition to a circular economy may change perceptions of what is essential and create new risk management challenges.

References

[1] Fuller et al (2022) Pollution and health: a progress update. Lancet. Available at: https://www.thelancet.com/journals/lanplh/article/PIIS2542-5196(22)00090-0/fulltext

[2] A chemicals strategy for a sustainable chemicals revolution (rsc.org)

[3] Persson et al (2022) Outside the Safe Operating Space of the Planetary Boundary for Novel Entities. *Environmental Science and Technology*. Available at: https://pubs.acs.org/doi/10.1021/acs.est.1c04158

[4] Matlin et al (2022) Chemistry must respond to the crisis of transgression of planetary boundaries. *Chemical Science*. Available at: https://pubs.rsc.org/en/content/articlelanding/2022/sc/d2sc03603g

[5] RSC PFAS Policy Position: Available on the RSC website at pfas-policy-position-dec-2021.pdf (rsc.org) and RSC EDC Policy position available at edc-policy-position-final-sep-2020.pdf (rsc.org)

[6] United Nations Environment Programme, *Decision IV/25: Essential uses*. Available at: https://ozone.unep.org/treaties/montreal-protocol/meetings/fourth-meeting-parties/decisions/decision-iv25-essential-uses

[7] Fischoff (1994) Acceptable Risk: A Conceptual Proposal. *Risk: Health, Safety & Environment*. Cambridge University Press.

[8] Health and Safety Executive (1988) *The Tolerability of Risk from Nuclear Power Stations*. HSE Books.

[9] Health and Safety Executive(2001) *Reducing Risk, Protecting People*. HSE Books.

[10] Collingridge (1980) *The Social Control of Technology*. St. Martin's Press.

[11] The views of the participants in the breakout sessions were diverse, and in summarising the discussions it is possible that not everyone's view is represented in the write up. This section does not represent the views of RSC or the other members of the organising committee.

[12] The Collingridge dilemma is the idea that because of uncertainties, risks cannot always be predicted before a technology has been fully developed, but once the technology is in use, it may be too late to avoid the risks.

Acknowledgements

Special thanks to the workshop organising committee:

Edward Latter and Gershwinder Rai (Defra)

Stavros Georgiou (Health & Safety Executive)

Roger Pullin (Chemical Industries Association)

Ragnar Lofstedt (Kings College London)

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Position statement

Per- and Polyfluoroalkyl Substances (PFAS) in UK Drinking Water

June 2023

PFAS are a class of substances with many useful properties for manufacturers and consumers, but these chemicals (and their degradation products) also have high persistence, are highly mobile, and can bioaccumulate in humans and wildlife. The RSC has previously advocated for risk-based regulation of PFAS.[i] Increasing concern about environmental persistence and toxicity of PFAS has spurred international regulators to impose stricter regulatory limits on the acceptable levels of PFAS in drinking water to limit human exposure and consequently prevent harm. In the UK, we must urgently address PFAS water pollution to minimise the potential for negative health effects today and in future generations. By implementing stronger regulatory controls on PFAS in drinking water, the UK has an opportunity to show international leadership in managing chemicals in the environment and furthering the UN Sustainable Development Goals (SDGs), especially SDG6 on clean water.

We recommend using a *Source-Pathway-Receptor* model for considering PFAS risks, with action required across government, industry, and the water sector:

Key Asks of Government

Ensure the many hundreds of *sources* of PFAS are reported and captured in a national inventory.

Identify, test, and regulatethe *pathways* of PFAS from factory emissions and product related waste to surface and ground waters through tighter environmental standards

To reduce the potential for harmful levels of PFAS to accumulate in the *receptor* of the human body, establish new statutory action standards for PFAS in drinking water of a maximum concentration of 10 ng/L per single PFAS and 100 ng/L for the overall summed concentration of all PFAS.

To manage PFAS pollution and risks effectively, given the widescale use of PFAS across sectors, the government needs a national chemicals regulator that brings greater cohesiveness and connectivity across government departments.

Key Asks of the UK Water Sector

Greater collaboration is needed across the water sector to harmonise and standardise measurement approaches, generate and publish PFAS in drinking water monitoring data across UK, and develop improved remediation solutions to meet stricter action standards for PFAS in drinking water. Sector bodies could help coordinate this effort.

Ensure that, as far as possible, the pollutor pays for the delivery of wholesome water. Based on evidence relating to sources of PFAS use in the UK, the use of PFAS is widespread across virtually all production sectors. The chemicals and related industries, water sector, and government should work together to provide a fair funding system so that polluters, rather than water consumers, pay for the monitoring and remediation activities required to meet new standards.

Background

Per-and Poly-fluoroalkyl Substances (PFAS) are a group of fluorinated chemicals that have water-, oil-, heat-, and stain-resistant properties. Due to the strength of the carbon-fluorine bond, PFAS resist degradation and have high stability, mobility, and persistence in nature. Used around the world since the 1940's, these chemicals have found their way into the environment and are now omnipresent in soil, ground water, surface water, and the polar ice caps. Evidence suggests that PFAS can bioaccumulate in wildlife and humans and some are known to pose a potential risk of toxicity, especially following local pollution incidents.[2,3,4,5,6,7,8] PFAS are used in a variety of sectors, as their unique properties provide value in manufacturing processes and consumer products. Estimates of the number of PFAS vary but may include anywhere from 4,700 to >10,000 substances.[9,10] The RSC uses the 2021 Organisation for Economic Co-operation and Development (OECD) definition for PFAS[1] which standardised the characterisation of such substances:

The OECD 2021 definition[11]

"Any fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e.with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF3) or a perfluorinated methylene group (–CF2–) is a PFAS"

The widespread, growing use and persistence of PFAS has made it difficult to manage these chemicals in the environment and for regulations to keep pace. Scarcity of data on PFAS uses and discharges, legacy contamination, and uncertain human health and environmental effects related to consistent low level exposure have all influenced the lack of action on this issue. However, given cases of observed effects from localised pollution by PFAS, regulators have increasingly recognised that PFAS require immediate attention because of their persistent, mobile, bioaccumulative, and potentially toxic nature.[12,13,14] Understanding and managing all aspects of PFAS use is a complex undertaking and is expected to take many years. The RSC laid out a potential future risk management framework for PFAS regulation, using the best scientific evidence, in a 2021 policy position.[15]

[1] The Health and Safety Executive, in its April 2023 PFAS Regulatory Management Options Analysis (RMOA), used a more refined subset of PFAS than in the OECD definition, reducing the scope of the analysis to hundreds of substances.

It is likely that the greatest risks of harm from PFAS exposure to wildlife and humans would be if toxic PFAS were ingested orally in harmful concentrations in food and drinking water. Therefore, to prioritise the minimisation of human exposure in the short term, regulators should first focus on investigating the evidence for the most common sources of and pathways to direct oral exposure to PFAS. This policy position focuses on contaminated drinking water as the most risky route of exposure to PFAS in the general population and the corresponding regulatory options that could improve management of PFAS in the environment.

Evidence for PFAS in UK waters and in UK Drinking Water

Following presentations at an RSC expert-led event on PFAS in water in November 2022, and the RSC's independent research, there is clear evidence to show that PFAS are present in UK surface and groundwaters.[16] However, environmental monitoring for PFAS has been patchy and inconsistent, using varied criteria for which PFAS are measured, and different analytical methods and limits of detection. Data from the Environment Agency (England & Wales), and more recently from research by Stéphane Horel presented in Le Monde (and other media outlets), indicate that there is widespread PFAS presence in water in the UK and elsewhere in Europe.

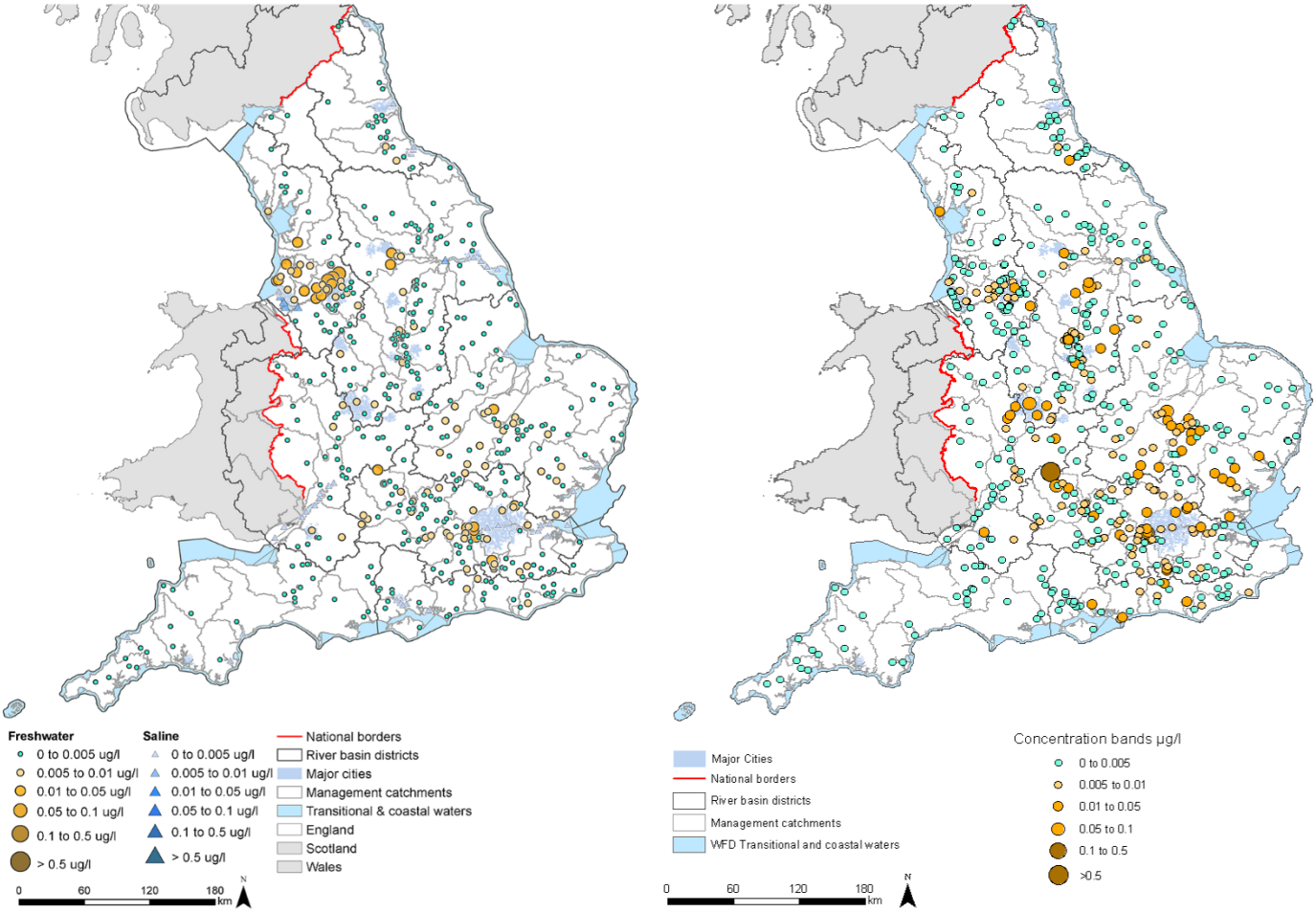

Figure 1 Sampling locations and mean measured PFOS (left) and PFOA (right) concentrations from Environment Agency surveillance monitoring programme (borrowed from EA 2021)

The EA has been conducting fully quantitative assessments of the levels of the two PFAS most known to be toxic and persistent, perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA), from

~500 sites across England (Figure 1).[2] They conclude that the PFAS problem appears widespread, with examples of hotspots.[17]

Data from the Le Monde analysis of ~1,700 samples also shows widespread presence of PFAS in the UK (Table 1). For approximately two thirds of sites, measurements of PFOS and PFOA are less than 10 ng/L in surface and ground waters. However, a third of sites measured between 10-100 ng/L of PFOS and PFOA, which is considered a medium risk by the Drinking Water Inspectorate (DWI) in the UK, and 3-4% are at levels designated by the DWI as requiring immediate remediation.[18]

	Total number of samples included in analysis	Percentage of samples less than 10 ng/L	Percentage of samples 10 ng/L to 100 ng/L	Percentage of samples greater than 100 ng/L (wholesomeness concentration exceeded)
PFOS	1644	63	33	4
PFOA	1768	65	32	3

Table 1 Le Monde data on PFAS in UK water

Based on the RSC expert-led event in November 2022 and ongoing consultation with our members, there is broad agreement that PFAS contamination of water is a growing and unchecked problem in the UK, but there is also much uncertainty around the true scale of the problem because of variance in analytical methods and lack of clear human health data on the majority of PFAS. Evidence from human biomonitoring has indicated that PFAS are present in and do accumulate in the human body.[19] Some evidence has also shown negative health outcomes from PFAS exposure, such as increased cholesterol, immune suppression, and possible mutagenic and carcinogenic effects. However, it would take many decades to generate new toxicology data for all PFAS using standard approaches.[20] The US EPA have begun a programme to test PFAS using new approach methods (NAMs), but this work is still ongoing.[21] In the interest of public safety, with today's knowledge about PFAS persistence, bioaccumulation, and toxicity, it is unfeasible to follow a classical toxicological paradigm to test all PFAS. Instead, the precautionary principle states that despite the uncertainty that still exists, robust and timely action – including good regulation – ought to be taken in order to protect consumers.

Current UK Regulatory Context

Current UK chemical regulations post EU-exit are not fit for the purpose of managing PFAS in the environment. Regulatory accountability for PFAS use in products, processes, and waste management is fragmented across government departments. To provide a holistic and consistent approach for wide-reaching topics such as PFAS pollution, the government would benefit from a national overarching regulator for chemicals management, such as a Chemicals Agency, that brings greater cohesiveness and connectivity across government departments.

This RSC policy position is timely, as the Department for Environment Food and Rural Affairs (Defra) and the Health and Safety Executive (HSE) have prioritised PFAS in the Great Britain REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) work programme for 2022-25. As part of this work, the HSE released a report (conducted by the Environment Agency (EA) for England & Wales) of the most appropriate regulatory management options (RMOA) in April 2023, which surveyed the current

[2] More detailed information on the full scope of EA monitoring can be found in the HSE's RMOA.

status of PFAS monitoring in the UK and existing regulation related to PFAS. Defra are also looking at the whole landscape of PFAS policy for England; some matters will be within devolved environment policy in Scotland, Wales, and Northern Ireland.

GB REACH is the primary method of regulating industrial chemicals in the GB market, but many PFAS fall outside the scope of the REACH registration process. The HSE notes in its RMOA that 'In UK REACH, there are 36 individual PFAS registered with the potential that 40 others could be registered by the final registration deadline. This does not provide the whole picture with respect to the PFAS market in GB as it is likely that some PFAS are manufactured or imported below the UK REACH registration threshold of 1 tonne / per year per manufacturer / importer, or that PFAS are present in finished or semi-finished goods.'[22]

These findings highlight the need for a more comprehensive approach to managing PFAS across the range of uses and potential routes of exposure. As a main pathway for human exposure to PFAS, and out of scope of current regulations such as REACH, drinking water is an ideal area to focus new methods of PFAS management. The RMOA came to the same conclusion, listing as a priority the 'Development of statutory standards for PFAS in drinking water in England and Wales.'[23]

UK Drinking Water Guidelines

The current approach regulates for individual PFAS in water. In October 2021 the Drinking Water Inspectorate (DWI), which covers England and Wales, released a list of 47 PFAS, including PFOA and PFOS, to be monitored in drinking water. Water companies must test their water sources for PFAS using fully accredited methods or, 'Where an analytical method is not fully accredited and an accredited method is not available, results must be flagged as being non-accredited.'[24] Results are mapped against the DWI's 3-tier system for managing risks from PFAS (table below). PFAS concentrations in Tier 1 constitute a low risk and no additional action needs to be taken. Tier 2 requires increased monitoring and preventative measures to avoid moving into Tier 3. Tier 3 is high risk, where PFAS are present in concentrations high enough to exceed wholesomeness standards (where presence of a substance constitutes a potential danger to human health). Tier 3 requires water companies to notify consumers and health authorities and take immediate action to remediate the water supply.[25]

Tier	Concentration of any single PFAS in final drinking water	Summary of actions (for a more detailed list, see DWI guidance)
Tier 1 – Low Risk	Less than 0.01 µg/L (10 ng/L)	Continue to monitor for PFAS and include in risk assessments
Tier 2 – Medium Risk	Less than 0.1 µg/L (100 ng/L)	Continue to monitor for PFAS, update risk assessments, review control measures, consult with health authorities
Tier 3 – High Risk (action standard)	Greater than or equal to 0.1 µg/L (100 ng/L)	Wholesomeness concentration exceeded: notify health authorities, fast-track resamples of water sources, review control measures and prepare emergency contingency measures to prevent the supply of water to consumers, increase frequency of future monitoring for at least 12 months

Table 2 DWI PFAS in water risk tiers and summary of actions

The tiered approach does allow for resources to be prioritised to the most at risk areas. Additionally, compared to efforts in other regions, the DWI's list of 47 PFAS is a much wider range of substances than is usually tested. However, while positive steps have been taken, the current testing regime ignores total PFAS concentration. Also, compared to new regulatory action being taken in other jurisdictions and the most up to date research on the risks to human health from PFAS, the current guideline value for a single PFAS concentration of >0.1 µg/L as a Tier 3 action standard is high.

International Regulatory Context

There has been a recent upsurge in efforts around the world to better define, monitor, regulate, and remediate the problems with PFAS. For example, these chemicals are considered an issue of concern in international chemicals policy forums such as the UN Strategic Approach to International Chemicals Management (SAICM).[26] Ideally, given the persistence and mobility of PFAS around the globe, a harmonised approach to PFAS standards in water should be developed. However, to date, the approach to managing PFAS differs across jurisdictions. While a comprehensive analysis of global PFAS action is outside the scope of this paper, the following section briefly explains the approaches in USA and EU.

USA

The United States Environmental Protection Agency (EPA) released a PFAS Strategic Roadmap in 2021 and has embarked on a work program including:

- restricting the future use of currently unused PFAS, through its 'significant new use rule'
- increased data collection on PFAS manufacture, use, disposal, and exposure
- updating pollution limits for and increasing monitoring of industrial discharges

The EPA has also introduced national drinking water limits for six PFAS: PFOS and PFOA will be regulated as individual contaminants at 4 ng/L each, and PFNA, PFHxS, PFBS, and GenX Chemicals will be regulated as a mixture not to exceed a designated hazard index.[27]

EU

The European Union has taken a variety of actions in recent years to control PFAS use and exposure to the environment, including:

- regulation of longer chain PFAS, PFHxS, and PFHxA, through EU REACH restriction
- an ECHA-endorsed plan to restrict all PFAS in firefighting foams
- a proposal to ban all (>10,000) PFAS (according to the OECD definition of PFAS) through the restriction process

In the 2021 update to the EU's Drinking Water Directive, two measures of PFAS are used to determine water quality. First, 'sum of PFAS' specifies 20 PFAS, of which the sum of concentrations must not exceed 100 ng/L. Second, 'total PFAS' sets a limit of 500 ng/L for the overall concentration of all PFAS present in water.[28]

European Food Standards Authority (EFSA) review of PFAS human heath data

The EFSA CONTAM panel reviewed the human health data for PFAS contamination of food in September 2020, and established a tolerable weekly intake (TWI) of 4.4. ng/kg bw/week, based on the sum of four PFASs: PFOS, PFOA, PFHxS and PFNA.[29] In this analysis in Europe, it was found that the mean lower bound exposure estimate in adolescent and adult age groups ranged from 3-22 ng/kg bw/week with the 95th percentile estimate from 9-70 ng/kg bw/week. This evaluation included a great deal of uncertainty, but it did indicate that based on the current evidence, exposures are thought to be higher than might be considered safe or acceptable.

Applying the TWI of 4.4. ng/kg bw/week in the context of drinking water intake, one would assume that a 70kg adult drinks 2 litres of water per day, equivalent to 14 litres of water a week. For a 70 kg adult, the TWI represents a weekly intake of 4.4 ng/kg bw/week x 70 kg = 308 ng/week. For an assumed weekly intake of 14 litres of water, this would equate to a safe level of 22 ng/L per day for a sum of the four PFASs: PFOS, PFOA, PFHxS and PFNA. However, there are other pathways of exposure, e.g. food intake, to take into account as well, justifying a slightly more conservative approach to water standards.

Current UK Committee on Toxicity position on the EFSA Opinion on PFAS

The Committee on Toxicity (COT) in the UK issued a statement on the EFSA opinion in October 2022 but have not yet recommended any health based guideline values for use in a UK context.[30] It is expected that the UK will perform its own evaluation of the data and, given the scale of the data package for PFAS and emerging new data from the US EPA, this may take some years to finalise.

Policy options

Proper regulatory and environmental management of PFAS will require action across the spectrum of government, industry, and the water sector. We use a source-pathway-receptor model from Sunderland et al (2019) to conceptualise the issue and identify priority areas for action.[31]

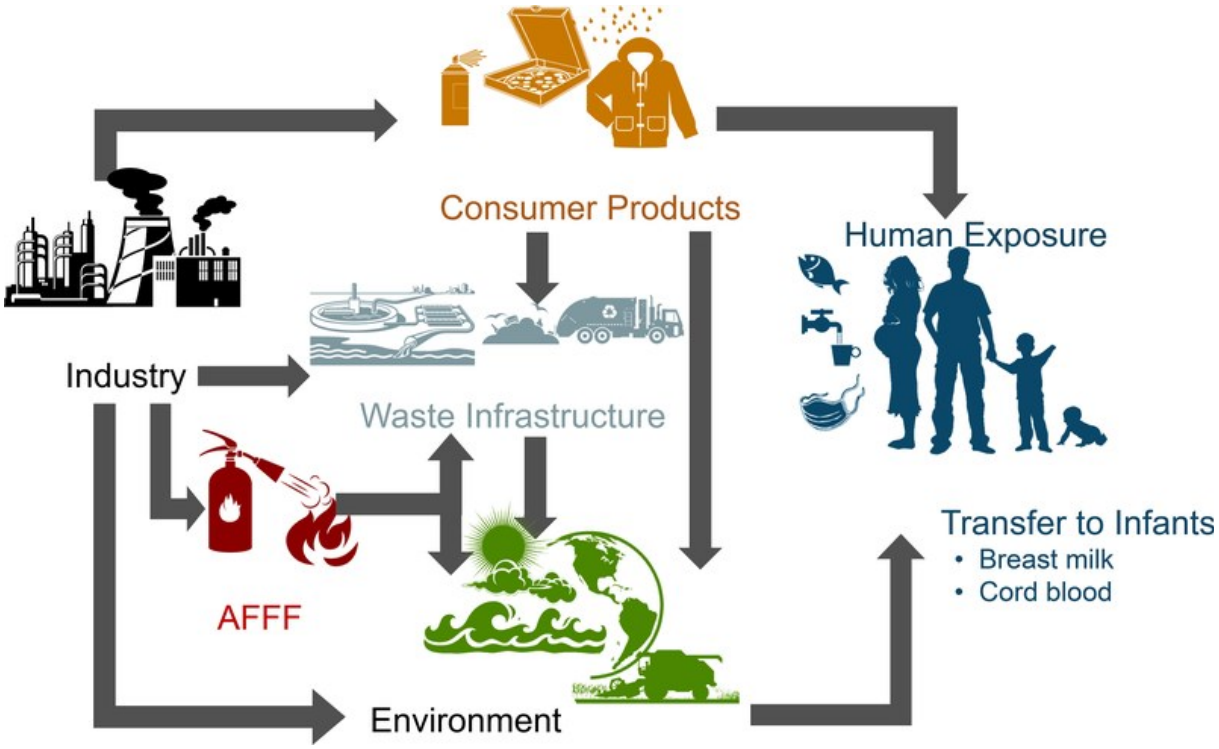

Figure 2 PFAS exposure pathways (borrowed from Sunderland et al 2019)

Ultimately, stopping or reducing pollution at the source is the most effective way to prevent humans and the environment from being exposed to harmful chemicals. In the meantime, current and legacy pollution must also be addressed by identifying and removing it from the environment, especially in drinking water. The following policy options address actions that can be taken in both areas to reduce the risk of human PFAS exposure.

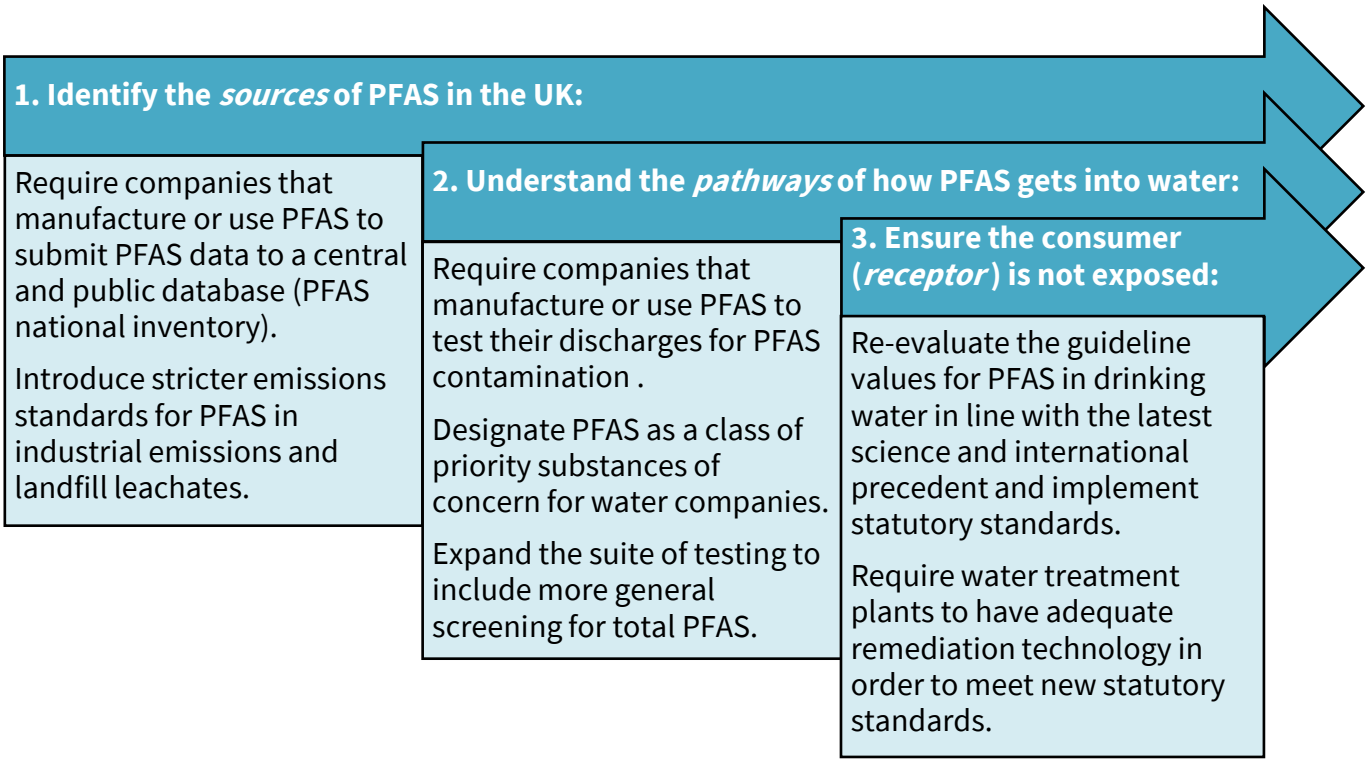

Figure 3 Policy options for the management of PFAS in UK drinking water

1. Identify the sources of PFAS in the UK:

Require companies that manufacture or use PFAS to submit data to a central and public database (PFAS national inventory).

Currently, information on the UK sources of PFAS from manufacture and use is difficult to access. The government and indeed wider industry do not have a record of where PFAS are present or being used across the supply chain. Standards for PFAS in products are difficult to get from manufacturers due to confidentiality concerns, and users do not always know or share the full picture of PFAS in their products. The HSE's PFAS RMOA (2023) concurs that 'the information available in GB is not able to provide a comprehensive picture of volumes, uses and PFAS used.'[32] Therefore, the first step towards better risk management of PFAS would be to require an audit of all PFAS manufacture and use across all industrial sectors and consumer products. This may also require testing and reporting of imported products. It is especially important to include substances that do not fall under the scope of UK REACH but within the OECD definition. The audit should also include null reporting.

Compiling such data in a central and accessible database will allow regulators to make decisions based on complete information about the sources of PFAS in the UK. Researchers and regulators can also better identify, prevent, and remediate potential water contamination sites if there is complete data on where PFAS is made and used. It is also important for companies to have better knowledge of their own PFAS use to fully control emissions. Requiring annual reporting will increase awareness in company management of the potential benefits and harms of PFAS use, transparency with regulators and the public, and opportunities to phase out PFAS and/or substitute to other substances. Fines could be imposed if companies do not perform adequate reporting on environmental emissions into UK waters.

2. Understand the pathways of how PFAS gets into water:

Require companies that manufacture or use PFAS to test their discharges for PFAS contamination.

With data from a national PFAS audit, as well as pre-existing data about existing PFAS hotspots, regulators should have a reference list of sites that are at a high risk of producing PFAS contamination. Regular testing for total PFAS and individual PFAS at sites with waste water discharges would help to identify any sources of pollution early on. Then, regulators and companies can take immediate action to limit the spread of the problem, including notifying downstream water treatment plants, so they can do extra monitoring and testing to ensure that drinking water remains to a high standard.

Monitoring of industrial emissions would also enable regulators to determine liability for localised PFAS pollution. Identifying the source of pollution is an important aspect of the polluter pays principle, which requires the responsible party to pay for the damage and clean-up of pollution incidents.[33] Exclusion of known point sources could also help pinpoint more disperse sources of contamination that may not be regulated or may indeed be non-compliant.

Introduce and enforce stricter emissions standards for PFAS in industrial emissions to water and landfill leachates.

The Environment Agency should implement stricter standards for PFAS in industrial emissions via its power to grant and amend environmental permits. In particular, these rules should require companies to use the best available techniques to minimise any emissions to the environment.[34] Landfill emissions permits should also be updated to include standards for PFAS in leachate.

New monitoring requirements for individual and total PFAS would generate the data needed to refine and enforce these new standards. Incidences of rule breaking could be fined via a similar approach to the current EA prosecutions of water and sewage companies, where fines are reinvested into environmental schemes. The fines need to be higher than the cost of implementing any new technology in order to be effective. Monies could also be directed toward PFAS-specific remediation projects.

This aligns with the goal published in the UK government's 25 year Environmental Improvement Plan (EIP), which aims to 'tackle chemical pollution at source through regulatory action.'[35] Rectifying pollution at its source is an important principle for managing chemicals in the environment.[36]

Designate PFAS as a class of priority substances of concern for water companies.

Water companies are tasked with monitoring and remediating many other existing contaminants, often resulting in limited resources to address PFAS. Formally designating PFAS as a class of priority substances will provide justification for the further expansion of monitoring capacity, method accreditation, and remediation efforts.

Designating PFAS (defined by the OECD definition) as priority substances of concern in water also aligns with UK commitments to the Stockholm convention on POPs, of which PFOA, PFOS, and PFHxS are listed substances (and long chain PFCAs are currently under consideration).[37,38]

Clarify testing methods for individual PFAS and expand the suite of testing to include more general screening for total PFAS.

Since 2021 when the DWI introduced the list of 47 PFAS for testing, water companies and laboratories have invested in improved analytical testing capabilities and standardised methods. However, methods for testing for PFAS in water are constantly evolving, and there are accredited analytical methods for only a limited number of substances. Currently, methods often vary from lab to lab, and data is not always comparable. The government could support the development of standardised and accredited methods for testing PFAS in the environment.

There are two main approaches to testing water for PFAS, by targeting PFAS as a group or as individual substances. The grouped approach evaluates the total amount of PFAS (or a reliable indicator for total PFAS, such as organic fluorine). The individual approach evaluates the concentration of specific well-defined substances. Both have pros and cons (see Table 3).

	Pros	Cons
Grouped approach	• Limits total amount of PFAS in water, capping total risk • More manageable amount of testing required	• May allow a more than desirable amount of any given substance, risking increased exposure and harms from the more toxic types of PFAS
Individual approach	• Ensures that PFAS deemed to be high risk are specifically monitored and remediated	• Too many substances to regulate everything on an individual basis – testing for each individual substance would be a burden • May miss out on substances that are toxic but because of lack of data have not yet been identified as high risk

Table 3 Grouped versus individual approach to testing for PFAS in water

A combination of both approaches is ideal, balancing the cost and resource burden of testing with the need to manage highest risk substances.

Testing for total PFAS can reveal hot spots that might be missed when testing for the current DWI list of 47 PFAS, which will allow researchers to better identify locations that require further investigation. This type of testing is important because the total number of potential PFAS is so vast; current testing regimes may ignore places where cumulative PFAS may be beyond healthy exposure levels, even if levels of individual PFAS do not trigger a contamination warning. Expanding the testing suite is also important because PFAS can transform once they are in the environment, resulting in the release of other substances of concern.[39] Testing only for a specific list of PFAS may allow these precursors/end-state substances to persist under the radar.

Regular water tests should include total PFAS methods, such as total organic fluorine (TOF) or total oxidisable precursor (TOP) assays,[40] in addition to targeted methods that identify the presence of specific PFAS. If total PFAS is much higher than the sum of the targets, the source should be flagged for further testing. Then, non-targeted methods can be used to identify the unknowns and update the list of targets for future monitoring.

3. Ensure the consumer (receptor) is not exposed to PFAS via drinking water:

Re-evaluate the current guideline values for PFAS in drinking water in line with the latest science and international precedent, and implement statutory action standards for water companies.

Approaches to setting limits for PFAS in drinking water vary between jurisdictions, with some countries or regions setting total PFAS limits and others setting maximum concentrations for each individual PFAS, or some combination of these methods.

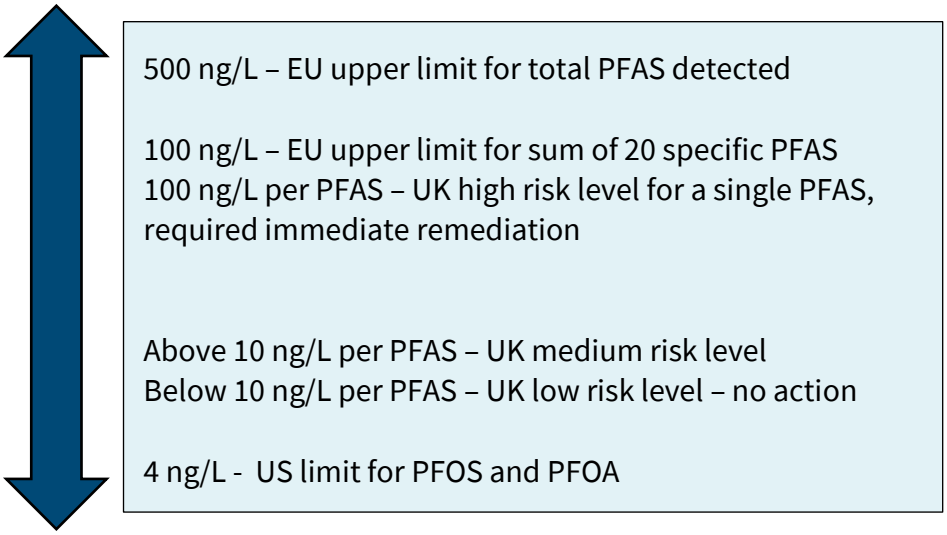

Figure 4 Current limits on PFAS concentration in drinking water in the UK, US, and EU

Currently in the UK, 47 different PFAS are measured and regulated individually, with a maximum level of 100 ng/L per PFAS. A new statutory action standard should lower the limit to 10 ng/L or lower per PFAS, and accredited analytical methods should be developed within the next few years to ensure this standard can be met for all of the DWI-listed individual PFAS. Compared to the current DWI Tier system, any measurement above 10 ng/L would be considered a Higher Risk, while Lower Risk would be 10 ng/L or less. Therefore, the new system would focus on bringing the whole of the UK population into a lower risk scenario. This approach aligns with the precautionary principle and lowers the likelihood of sustained exposure to PFAS. Water companies would be required to remediate down to 10ng/L or less in order to meet wholesomeness requirements, according to the current Tier 3 guidelines.

Tier	Current DWI guidance*	Proposed statutory standards*
Tier 1 – Low Risk	Less than 0.01 µg/L (10 ng/L)	Less than or equal to 0.01 µg/L (10 ng/L)
Tier 2 – Medium Risk	Less than 0.1 µg/L (100 ng/L)	Tier eliminated
Tier 3 – High Risk (action standard)	Greater than or equal to 0.1 µg/L (100 ng/L)	Greater than 0.01 µg/L (10 ng/L) – triggers remediation action

*for measurement of a single PFAS

Table 4 Existing DWI guidelines versus proposed statutory standards

Additionally, a new PFAS action standard should be established which sets a maximum acceptable concentration of 100 ng/L of either a sum of PFAS or total PFAS, using methods as described earlier in this

report. There are two options for this standard: sum of PFAS, which looks for the sum of concentrations of a defined list of PFAS, or total PFAS, which looks for the total amount of PFAS present without identifying individual substances.

If using the sum of PFAS method, there are two further options for determining the list of substances. First, the regulator could use the current DWI list of 47 PFAS, which would align this standard with the current testing regime. Alternatively, the list of 20 PFAS from the EU sum of PFAS standard could be used. It could be useful, given the persistence and mobility of PFAS in rivers and seas and the EU being our closest geographical neighbour, to harmonise these standards as much as possible.

Water companies that measure levels in drinking water above 100 ng/L using sum or total PFAS methods would be required to remediate immediately to 100 ng/L or less, according to the actions currently prescribed in DWI rules for Tier 3.

Final drinking water should meet all requirements for individual and total PFAS in order to meet a definition of 'wholesome' for the consumer. Such an approach to regulation would assure the best protection for human health now and for future generations, and it would contribute to meeting the sustainable development goals for water quality.

Figure 5 Requirements for final drinking water to be considered wholesome

Require water treatment plants to have adequate remediation technology in order to meet new statutory standards.

Conventional water treatment systems are not always equipped to remove PFAS effectively, nor is it proven that existing strategies are effective. Also, PFAS-containing sewage sludge from wastewater treatment plants is often spread on land or transferred to landfill, where PFAS are rereleased into the environment. Commonly used methods for filtering PFAS out of drinking water supplies include activated carbon, ion exchange, and membrane filtration, which result in PFAS-laden waste that must be treated or disposed of without rereleasing PFAS into the environment. Also, there is currently limited available information to judge their effectiveness and cost in water treatment facilities, and further information is urgently needed.

Within a reasonable timeframe, water treatment plants should be required to have technology in place that can adequately remediate water to the lowest levels defined by new statutory standards. It is understood from our research that new technologies are available for this purpose; however, concern remains about the cost of implementation, especially as water companies are being made to address a problem that stems from outside sources. Companies should also prepare plans for the management and appropriate disposal of filter or other wastes that may contain concentrated PFAS, in order to lessen the risk of PFAS re-entering the environment.

Although it is out of scope for this policy position to have a full discussion of the available remediation technologies, it is important to support the continued research, development, and commercialisation of new methods for remediating and destroying PFAS such that they do not pollute the environment. Currently, UK investment in new technologies is difficult to obtain for entrepreneurial SMEs. There are opportunities for collaboration between industry, academia, and the water sector to innovate in this space. Regulatory tools and new standards can also be used to incentivise change – for example, producers and users of PFAS could be made to pay a levy per unit of PFAS used, which could encourage them to look for alternatives to PFAS and fund effective end of life management of PFAS in the waste and water systems.

Final thoughts on policy implementation

The actions laid out in this policy position are not linear. Some, such as a national PFAS inventory, will take time to develop. Others can and should be implemented at the earliest opportunity. Importantly, a precautionary approach requires that we do not wait to take action where possible, based on the scientific evidence we have today. Our approach is focused on human consumers and drinking water. Stricter controls of factory emissions at source will also enhance the quality of water for wildlife and make the downstream remediation of water by the water sector to meet drinking water standards an easier challenge.

Additionally, PFAS are mobile in water, so pollution in the UK could originate internationally in addition to known domestic sources. These policy options are described in the context of the UK, but we would advocate that these policy options can be applied in any jurisdiction. If all of the world adheres to stricter action standards, the global burden of PFAS pollution in water and as measured in human beings and wildlife will reduce over the years ahead.

The UK has an opportunity to be a leader in this area by taking decisive regulatory action now. We would like to see the formation of a collaborative PFAS action group involving government, academia, PFAS manufacturing, product manufacturing industry, and the water sector – to develop joint funding solutions, reduce factory emissions using the best available technology, improve monitoring of PFAS in water, and increase the use of water remediation technologies to assure new standards for drinking water can be met.

Contact

The Royal Society of Chemistry would be happy to discuss any of the issues raised in our statement in more detail. Any questions should be directed to the RSC Policy & Evidence Team at [redacted]@rsc.org. This document was prepared by Stephanie Metzger with support from Camilla Alexander-White and Geena Goodwin of the RSC Policy & Evidence Team. Our position was developed following an RSC engagement event in November 2022 with members of the RSC and the wider international scientific community. Special thanks to Sue Bullock, Daniel Brown, Rebecca Miller, and Mike Padgham of TSG Consulting for providing scientific evidence and to expert reviewers Dr. David Megson, Dr. Stephen Mudge, and Prof. Tom Welton.

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1 RSC (2021) Risk-based regulation for per- and poly-fluoroalkyl substances (PFAS). https://www.rsc.org/globalassets/22-new-perspectives/sustainability/a-chemicals-strategy-for-a-sustainable-chemicals-revolution/pfas-policy-position-dec-2021.pdf

2 Jian J, Chen D, Han F, Guo Y, Zeng L, Lu X, Wang F (2018) A short review on human exposure to and tissue distribution of per- and polyfluoroalkyl substances (PFASs). Science of the Total Environment, 636, 1058-1069. https://doi.org/10.1016/j.scitotenv.2018.04.380

3 CDC (2021) Toxicological Profile for Perfluoroalkyls. https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237

4 PFAS in UK Drinking Water Event slide deck (2022) https://cdn.eventsforce.net/files/ef-b3cjs6i56sls/website/2659/rsc_pfas_contamination_in_uk_water_workshop_slide_deck.pdf

5 Committee on Toxicity (2022) Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food. https://cot.food.gov.uk/sites/default/files/2022-10/PFAS%20final%20draft%20statement%20V2_September%202022_AB_OOS%20-%20SW%20Updated%2017-10-22.pdf

6 Sunderland E, Hu X, Dassuncao C, Tokranov A, Wagner C, Allen J (2019) A Review of the Pathways of Human Exposure to Poly- and perfluouroalkyl Substance (PFASs) and Present Understanding of Health Effects. Journal of Exposure Science and Environmental Epidemiology. 29, 131-147. https://doi.org/10.1038/s41370-018-0094-1

7 RSC (2021) Risk-based regulation for per- and poly-fluoroalkyl substances (PFAS). https://www.rsc.org/globalassets/22-new-perspectives/sustainability/a-chemicals-strategy-for-a-sustainable-chemicals-revolution/pfas-policy-position-dec-2021.pdf

8 EFSA (2020) Risk to human health related to the presence of perfluoroalkyl substances in food. https://www.efsa.europa.eu/en/efsajournal/pub/6223

9 Williams A, Gaines L, Grulke C, et. al. (2022) Assembly and Curation of Lists of Per- and Polyfluoroalkyl Substances (PFAS) to Support Environmental Science Research. Frontiers in Envrionmental Science.10, 1-13. https://doi.org/10.3389/fenvs.2022.850019/

10 US EPA (n.d.) PFAS Master List of PFAS Substances. https://comptox.epa.gov/dashboard/chemical-lists/PFASMASTER

11 OECD (2021), Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD Series on Risk Management, No. 61, OECD Publishing, Paris.

12 Hale S, Arp H, Schliebner I, Neumann M (2020) **Persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances pose an equivalent level of concern to persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances under REACH. Environmental Sciences Europe. 32(155).** https://enveurope.springeropen.com/articles/10.1186/s12302-020-00440-4

13 Uhl M, Schoeters G, Govarts E, et. al. (2023) PFASs: What can we learn from the European Human Biomonitoring Initiative HBM4EU. International Journal of Hygiene and Environmental Health. 250. https://doi.org/10.1016/j.ijheh.2023.114168

14 PFAS in UK Drinking Water Event slide deck (2022) https://cdn.eventsforce.net/files/ef-b3cjs6i56sls/website/2659/rsc_pfas_contamination_in_uk_water_workshop_slide_deck.pdf

15 RSC (2021) Risk-based regulation for per- and poly-fluoroalkyl substances (PFAS). https://www.rsc.org/globalassets/22-new-perspectives/sustainability/a-chemicals-strategy-for-a-sustainable-chemicals-revolution/pfas-policy-position-dec-2021.pdf

16 PFAS in UK Drinking Water Event slide deck (2022) https://cdn.eventsforce.net/files/ef-b3cjs6i56sls/website/2659/rsc_pfas_contamination_in_uk_water_workshop_slide_deck.pdf

17 Environment Agency (2021) Poly- and perfluoroalkyl substances (PFAS): sources, pathways and environmental data. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012230/Poly-_and_perfluoroalkyl_substances_-sources_pathways_and_environmental_data_-_report.pdf

18 Dagorn G, Aubert R, Horel S, Martinon L, Steffen T (2023) 'Forever pollution': Explore the map of Europe's PFAS contamination. https://www.lemonde.fr/en/les-decodeurs/article/2023/02/23/forever-pollution-explore-the-map-of-europe-s-pfas-contamination_6016905_8.html

19 Committee on Toxicity (2022) Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food. https://cot.food.gov.uk/sites/default/files/2022-10/PFAS%20final%20draft%20statement%20V2_September%202022_AB_OOS%20-%20SW%20Updated%2017-10-22.pdf

20 RSC (2021) Risk-based regulation for per- and poly-fluoroalkyl substances (PFAS). https://www.rsc.org/globalassets/22-new-perspectives/sustainability/a-chemicals-strategy-for-a-sustainable-chemicals-revolution/pfas-policy-position-dec-2021.pdf

21 US EPA (2021) New Approach Methods Work Plan. https://www.epa.gov/system/files/documents/2021-11/nams-work-plan_11_15_21_508-tagged.pdf

22 UK HSE (2023) Analysis of the most appropriate regulatory management options (RMOA). https://www.hse.gov.uk/reach/assets/docs/pfas-rmoa.pdf

23 UK HSE (2023) Analysis of the most appropriate regulatory management options (RMOA). https://www.hse.gov.uk/reach/assets/docs/pfas-rmoa.pdf

24 DWI (2022) Risk assessments under regulation 27 and associated reports under regulation 28 of the Water Supply (Water Quality) Regulations 2016 (2018 in Wales) for Poly and Perfluorinated Alkyl Substances (PFAS). https://dwi-content.s3.eu-west-2.amazonaws.com/wp-content/uploads/2023/01/13123351/IL_03-2022_PFAS_Guidance-4-1.pdf

25 DWI (2022) Risk assessments under regulation 27 and associated reports under regulation 28 of the Water Supply (Water Quality) Regulations 2016 (2018 in Wales) for Poly and Perfluorinated Alkyl Substances (PFAS). https://dwi-content.s3.eu-west-2.amazonaws.com/wp-content/uploads/2023/01/13123351/IL_03-2022_PFAS_Guidance-4-1.pdf

26 UN SAICM (n.d.) Perfluorinated Chemicals. https://saicmknowledge.org/epi/perfluorinated-chemicals

27 EPA (2023) Proposed PFAS National Primary Drinking Water Regulation. https://www.epa.gov/system/files/documents/2023-04/PFAS%20NPDWR%20Public%20Presentation_Full%20Technical%20Presentation_3.29.23_Final.pdf

28 European Parliament (2020) 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). https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020L2184

29 EFSA (2020) Risk to human health related to the presence of perfluoroalkyl substances in food. https://www.efsa.europa.eu/en/efsajournal/pub/6223

30 Committee on Toxicity (2022) Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food. https://cot.food.gov.uk/sites/default/files/2022-10/PFAS%20final%20draft%20statement%20V2_September%202022_AB_OOS%20-%20SW%20Updated%2017-10-22.pdf

31 Sunderland E, Hu X, Dassuncao C, Tokranov A, Wagner C, Allen J (2019) A Review of the Pathways of Human Exposure to Poly- and perfluouroalkyl Substance (PFASs) and Present Understanding of Health Effects. Journal of Exposure Science and Environmental Epidemiology. 29, 131-147. https://doi.org/10.1038/s41370-018-0094-1

32 UK HSE (2023) Analysis of the most appropriate regulatory management options (RMOA). https://www.hse.gov.uk/reach/assets/docs/pfas-rmoa.pdf

33 RSC (2020) Principles for the management of chemicals in the environment. https://www.rsc.org/globalassets/04-campaigning-outreach/tackling-the-worlds-challenges/environment/rsc_principles_for_chemicals_in_the_environment.pdf

34 Defra (2022) New framework announced to tackle industrial emissions across the UK. https://www.gov.uk/government/news/new-framework-announced-to-tackle-industrial-emissions-across-the-uk

35 Defra (2023) Environmental Improvement Plan 2023. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1133967/environmental-improvement-plan-2023.pdf

36 RSC (2020) Principles for the management of chemicals in the environment. https://www.rsc.org/globalassets/04-campaigning-outreach/tackling-the-worlds-challenges/environment/rsc_principles_for_chemicals_in_the_environment.pdf

37 Secretariat of the Stockholm Convention (n.d.) PFASs listed under the Stockholm Convention. http://chm.pops.int/Implementation/IndustrialPOPs/PFAS/Overview/tabid/5221/Default.aspx

38 Defra (2023) Environmental Improvement Plan 2023. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1133967/environmental-improvement-plan-2023.pdf

39 Cousins I, DeWitt J, Glüge J, et. al. (2020) The High Persistence of PFAS is Sufficient for their Management as a Chemical Class. Environmental Science: Processes & Impacts. 22(12), 2307-2312. https://doi.org/10.1039%2Fd0em00355g

40 McDonough C, Guelfo J, Higgins C (2019) Measuring Total PFASs in Water: The Tradeoff between Selectivity and Inclusivity. Current Opinion in Environmental Science and Health. 7, 13-18. https://doi.org/10.1016/j.coesh.2018.08.005