POLY AND PERFLUOROALKYLATED SUBSTANCES (PFAS); THE GATHERING STORM FOR CHEMICAL REGULATORY PROFESSIONALS AND THE INDUSTRY

What are PFAS?

Per- and polyfluoroalkylated substances (PFAS) are a very large and structurally diverse group of man-made organo-fluorine substances. They are sometimes termed 'forever chemicals' because of their extreme persistence. Well known examples of PFAS are perfluoroctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), both of which are now subject to regulatory restrictions because of their harmful properties.

The OECD[1] global working group on PFAS defines this group of chemicals as *"fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it)…any chemical with at least a perfluorinated methyl group (−CF3) or a perfluorinated methylene group (−CF2−) is a PFAS"*. This definition is based purely on chemical structure. Identification of a substance as a PFAS does not necessarily mean that it is toxic[1]. Estimates of the number of substances that meet the PFAS definition vary from 4,700[1] to over 6,000,000[2]. The number of PFAS in commercial use and supply in the UK is unknown but likely to be much lower[3].

PFAS have been in commercial production and use since the mid-20th century. They were first used in fire-fighting foams in the 1960s. They are used globally in many industrial applications and consumer products. Their high thermal and chemical stability and their water- and oil-repellent nature encouraged their wide use in consumer products such as cosmetics, coatings for textiles and paper including food contact materials. PFAS also have many industrial applications including metal electroplating, polymer and semi-conductor manufacture amongst many more.

Why are they a concern?

PFAS are extremely stable because the carbon-fluorine bond is very strong. Their extreme persistency means that environmental exposure could be irreversible and that PFAS are technically difficult and costly to clean-up and destroy. Many PFAS are environmentally mobile and travel far from their source, leading to widespread contamination of environmental waters including sources used for drinking water supply. Shorter chain PFAS with a fluoroalkyl chain less than six carbon atoms are more mobile than longer chain substances and are frequently found in environmental waters including those used for drinking water supply. Longer chain PFAS have a greater propensity to bioaccumulate in the food chain, with reports of PFAS in human tissue and blood, in plants following uptake from soil and in animals such as fish. A recent European biomonitoring study[4] found that serum levels of PFAS exceeded safe thresholds in over 14% of teenagers sampled.

Exposure to some PFAS has been associated with a range of adverse effects on human health. These include altered immune and thyroid function, increased cholesterol, liver disease, reduced birth weight and adverse reproductive and development outcomes[4]. However, for most PFAS there is very little toxicological data. This is a high priority evidence gap that both scientists and regulatory authorities are seeking to rapidly address globally.

With so many uses of PFAS, there are numerous pathways of release to the environment across the full life-cycle of the substance from manufacture through use to disposal. PFAS are ubiquitous in the environment with contamination of remote areas by some PFAS reported. Higher environmental concentrations of PFAS are often associated with their use in firefighting foams at airports, fire training grounds, military sites, and major incident sites. Secondary sources of PFAS to the environment include wastewater treatment works and landfill sites. Research has been on-going in the UK by the Environment Agency to identify high risk sites associated with PFAS use. A useful summary of the evidence base on use and environmental occurrence of PFAS in England was published by the Environment Agency in 2021[3], with further sampling for a broader range of PFAS continuing in groundwater and surface waters planned.

Current and future UK and European PFAS policy

The hazardous and potentially ubiquitous nature of several PFAS has been recognised since the early 2000s when PFOS was voluntarily withdrawn from use by industry. Several PFAS are subject to global regulatory restrictions. PFOS was designated as a persistent pollutant (POP) under the Stockholm Convention[6] in 2009, followed by PFOA in 2020 and perfluorohexane sulfonate (PFHxS) in 2022. In addition, several PFAS are identified under the REACH regulations[7] as Substances of Very High Concern (SVHC) and subject to restrictions on manufacture, supply and use in the European Union and the UK. Concerns related to the persistent, bioaccumulative and toxic (PBT) properties of PFAS historically underpinned these restrictions. More recently, the high persistence and high mobility of PFAS have led to restrictions of other PFAS such as hexafluoropropylene oxide dimer acid (HFPO-DA) also known as Gen-X, based on an 'equivalent

[1] OECD (2021) Reconciling the terminology of the universe of per- and polyfluoroalkyl substances: recommendations and practical guidance

[2] Schymanski, E. P. Chirsir, T.Kondic, P. Thiessen, J. Zhiang & E. Bolton. PFAS and Fluorinated Compounds in PubChem. Online at https://t.co/UJtd55ntye

[3] Poly- and perfluoroalkyl substances (PFAS):sources, pathways and environmental occurrence. Environment Agency Chief Scientist's group report. Published 2021

[4] HBM4EU policy brief - PFAS. June 2022

[5] S.E. Fenton, A Ducatman, A Boobis, J. C. DeWitt, C. Lau, C Ng,J.S. Smith,and S.M. Roberts (2020) Per-and Polyfluoroalkyl Substance Toxicity and HumanHealth Review: Current State of Knowledge and Strategies for Informing Future Research. Environmental Toxicology and Chemistry—Volume 40, Number 3—pp. 606–630, 2021

[6]Persistent organic pollutants (POPs) | UNEP - UN Environment Programme

level of concern'. A substance-by-substance approach to risk management has led to several cases of regrettable substitution, with one hazardous substance being replaced by another. For example, the restriction prohibiting use of PFOS in fire-fighting foam led to replacement with shorter chain PFAS chemistries which are now known to have equally undesirable properties and are widely detected in environmental waters and soil.

The regulatory landscape is changing very rapidly with much tighter legislation anticipated including widespread restrictions on manufacture and use of PFAS in the EU, as well as other global jurisdictions. The scale of environmental contamination, the extreme persistency and harmful properties and the large number of PFAS has led the European Commission to making a commitment in 2020 in its Chemical Strategy for Sustainability, to phase out all non-essential uses of PFAS. In January 2022, a REACH restriction dossier was submitted on the use of PFAS in firefighting foams and five European Member States have very recently submitted a restriction proposal to the European Chemical Agency (ECHA) to restrict all other uses of PFAS, known as the 'universal restriction'. ECHA will publish the proposal on 7th February 2023 and a six-month consultation is planned to commence on 22 March 2023.

In the UK a regulatory management options analysis (RMOA) is currently being prepared under UK REACH regulations by the Environment Agency and is expected to be published in early 2023. It is not yet known if the UK will follow the same approach as the EU and propose a 'universal ban' on all PFAS or target specific uses or groups of PFAS.

The EU Water Framework Directive (WFD) and Environmental Quality Standards Directive currently lists only one PFAS – PFOS as a priority hazardous substance, with a biota based Environmental Quality Standard (EQS) of 9.1µg/kg wet weight and annual average EQS in water of 6.5 x 10^{-4} µg/l for inland surface waters and 1.3 x 10^{-4} µg/l for other surface waters. It is evident that when considering risk management of PFAS, the issue is far broader than PFOS. The Scientific Committee on Health, Environment and Emerging Risks (SCHEER) recently published an opinion[9] on a proposal for additional EQS for several PFAS under the WFD. It is not yet known if the UK will follow a similar route and develop additional EQS for PFAS, but it is likely given the wider awareness and supporting evidence base to indicate PFAS require wider risk management than simply focusing on a single substance, PFOS.

The recast European Drinking Water Directive[10] specifies thresholds for both sum of PFAS and total PFAS. In the UK, the Drinking Water Inspectorate (DWI) have recently published updated guidance on tiered risk assessment for PFAS[11] ; requiring water companies to identify sources of PFAS in their catchments and assess risk by considering proximity to sources, catchment flows, and hydrological conditions.

Managing the risk to the environmental and public health risks from PFAS is a significant global challenge requiring actions to tackle both legacy contamination from historical use of withdrawn substances and manage emissions from currently used PFAS. The scientific understanding and evidence base on hazards and effective approaches to managing risk and cleaning up existing contamination are rapidly evolving.

[7]Reg (EC) 1907/2006 concerning the registration, evaluation, authorisation and restriction (REACH) of chemicals)
[8]Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy
[9]SCHEER - Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - PFAS (europa.eu)
[10]Directive (EU) 2020/2184 of the European Parliament and of the council on the quality of water intended for human consumption
[11]Drinking water Inspectorate information letter to water companies July 2022

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