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INTERIM POSITION PAPER PER- AND POLY-FLUOROALKYL SUBSTANCES (PFAS) IN DRINKING WATER

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HSE NATIONAL DRINKING WATER GROUP

Contents

1.	Introduction	. 2
2.	Background	. 2
2.1	What are PFAS?	. 2
2.2	Chemical Structure of PFAS	. 2
2.3	How are PFAS used?	.3
2.4	How long do PFAS remain in the body?	.3
3.	Exposure Sources	.4
4.	Potential Health Effects of PFAS Exposure	.5
5.	How can PFAS enter Drinking Water Supplies?	.6
	How can PFAS enter Drinking Water Supplies? Can Drinking Water contaminated with PFAS be treated?	
		.6
5.1	Can Drinking Water contaminated with PFAS be treated?	.6 .7
5.1 6.	Can Drinking Water contaminated with PFAS be treated? Regulation of PFAS and Guideline Limits in Drinking Water	.6 .7 .8
5.1 6. 7. 8.	Can Drinking Water contaminated with PFAS be treated? Regulation of PFAS and Guideline Limits in Drinking Water Conclusion	.6 .7 .8 .8
5.1 6. 7. 8. Refe	Can Drinking Water contaminated with PFAS be treated? Regulation of PFAS and Guideline Limits in Drinking Water Conclusion Recommendations	.6 .7 .8 .8

This position paper has been developed by the Health Service Executive (HSE) National Drinking Water Group. It provides a summary, based on current best evidence, of the issues in relation to Per- and Poly-fluoroalkyl Substances (PFAS) in drinking water including potential health impacts and legislation. As PFAS are regarded as an emerging chemical threat, further scientific evidence is likely to be published in the short and medium term.

1. Introduction

Per-and poly-fluoroalkyl substances (PFAS) are a very large group of man-made environmentally and biologically persistent chemicals used in many industrial and consumer products since the 1950s (1). Approximately 4,700 PFAS have been identified to date, the two most well-known of which are perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) (1,2). PFAS are of concern because of their high persistence (or that of their degradation products) in the environment, and their potential impact on human and environmental health (1,3). The new *EU Drinking Water Directive* (EU 2020/2184) includes limits for PFAS in drinking water and will come into law in Ireland in January 2023 (1).

Many PFAS are water-soluble and can pass through soil and enter groundwater. They also persist in the environment, making it possible that exposure continues after active releases have discontinued. PFAS have also been shown to bioaccumulate in living organisms (4).

National monitoring activities in countries across Europe have detected PFAS in the environment, and production and use of PFAS in products has resulted in the contamination of drinking water supplies in several European countries (2).

2. Background

2.1 What are PFAS?

Per-and poly-fluoroalkyl substances (PFAS) belong to a group of chemicals known as persistent organic pollutants (POPs). Other POPs include polybrominated diphenyl ethers (PBDEs), polychlorinated biphenyls (PCBs), and organochlorine (OC) pesticides (5). Commonly studied PFAS include: Perfluorooctane sulfonic acid (PFOS), Perfluorooctanoic acid (PFOA), Perfluorhexane sulfonic acid (PFHxS), and Perfluorononanoic acid (PFNA) (6).

2.2 Chemical Structure of PFAS

PFAS are characterised by a fully or partially fluorinated carbon chain, and some have a hydrophilic tail (6–8). They are not naturally occurring in the environment and some PFAS are characterised as long-chain compounds, while others are short-chain compounds (8). The carbon-fluorine (C–F) bonds lead to very stable substances, a feature that makes the terminal transformation products of PFAS very persistent in the environment (3). The long-chain PFAS accumulate in humans, animals and sediment/soil, while the short-chain PFAS tend to accumulate in the environment due to their persistency and high mobility in air and water (2).

2.3 How are PFAS used?

- PFAS are synthetic chemicals that have the ability to reduce friction and are used in a variety of industries including aerospace, automotive, construction, and electronics (8).
- They are used to make fluoropolymer coatings and products that resist heat, oil, stains, grease, and water (9).
- In a recent non-exhaustive overview of the uses of PFAS, more than 200 use categories and subcategories for more than 1,400 individual PFAS were identified. In addition to well-known use categories such as textile impregnation, fire-fighting foam, and electroplating, the identified use categories also included: PFAS in ammunition, climbing ropes, guitar strings, artificial turf, and soil remediation (3).
- Some other specific products that may contain PFAS include (10):
 - Some grease-resistant paper, fast food containers/wrappers, microwave popcorn bags, pizza boxes, and sweet wrappers
 - Non-stick cookware
 - Stain resistant coatings used on carpets, upholstery, and other fabrics
 - Water resistant clothing
 - Cleaning products
 - Personal care products (shampoo, dental floss) and cosmetics (nail polish, eye makeup)
 - Paints, varnishes, and sealants

Limited information is available regarding which specific PFAS are used in which applications and at what levels in Europe (2). PFAS exposure is associated with an increased risk of some adverse effects for human health – c.f Section 4. Risks differ among different PFAS based on their potential toxicity, mobility, and bioaccumulation (8).

2.4 How long do PFAS remain in the body?

PFAS bind to proteins and partition to phospholipids in the body (11) and some PFAS remain in the body for a long time (8). The biological half-life of a chemical is the amount of time it takes for 50% of the substance to be eliminated from the body by natural processes (8,12). The biological half-life of PFAS vary by chemical species, however studies have shown long half-lives in humans for certain PFAS, for example (8,13–17):

- 3.3 to 27 years for perfluorooctane sulfonic acid (PFOS)
- 2.1 to 10.1 years for perfluorooctanoic acid (PFOA)
- 4.7 to 35 years for perfluorohexane sulfonic acid (PFHxS)

Human biomonitoring studies have detected a range of PFAS in the blood of European citizens (2). These studies have demonstrated that while levels for PFOA and PFOS (the most prevalent, studied and regulated PFAS) are decreasing, levels of more 'novel' PFAS are increasing (2).

3. Exposure Sources

People can be exposed to PFAS directly (via diet, drinking water, consumer products, etc.) and indirectly through transformation of certain precursor substances such as polyfluoroalkyl phosphate esters (PAPs)(11). The widespread use of PFAS over the past decade implies that most people are now exposed to these chemicals to some extent - in food, drinking water, house dust, indoor and outdoor air and certain consumer products (4) (see Figure 1 below).

For the general population, *ingestion* of PFAS is the primary exposure pathway (8). Major ingestion sources for PFAS include (4,8):

- Consuming food produced in areas contaminated by PFAS, in particular fish caught in contaminated water (as well as consumption of meat, fruit and eggs originating from, grown, or raised in PFAS contaminated water or soil).
- Eating food packaged in materials containing PFAS (e.g., popcorn bags and fast food containers).
- **Drinking contaminated water** (which may occur near manufacturing facilities that have used PFAS or in areas exposed to firefighting foams containing PFAS, including military bases and training sites).

Other exposure routes include *inhalation*, *dermal absorption* and *transplacental* (4,8):

- <u>Inhalation</u>: Breathing in PFAS-contaminated dust (e.g., dust can be contaminated by particles and fibres from carpets, upholstery, clothing, and other PFAS treated products like certain fabric sprays, and from soil).
- <u>Dermal Absorption</u>: Absorption of PFAS through the skin is limited and is of less concern as an exposure route. Showering and bathing or washing dishes in water containing traces of PFAS is not likely to increase exposure.
- <u>Transplacental</u>: Some PFAS have been shown to cross the placenta and enter umbilical cord blood. Different PFAS have varying levels of permeability to the placental barrier.

For infants and toddlers PFAS sources include (8):

- Breastmilk from women who have been exposed to PFAS (Of note: The level of exposure is dependent upon both the level of PFAS in the mother and the duration of breastfeeding (8). Breastfeeding mothers should continue to breastfeed (4,10). Despite potential PFAS exposure from breastmilk, breastfeeding has important benefits for the infant, including immunologic gains, and breastfeeding is good for the heath of both infants and mothers (8)).
- Infant formula reconstituted with PFAS contaminated water.



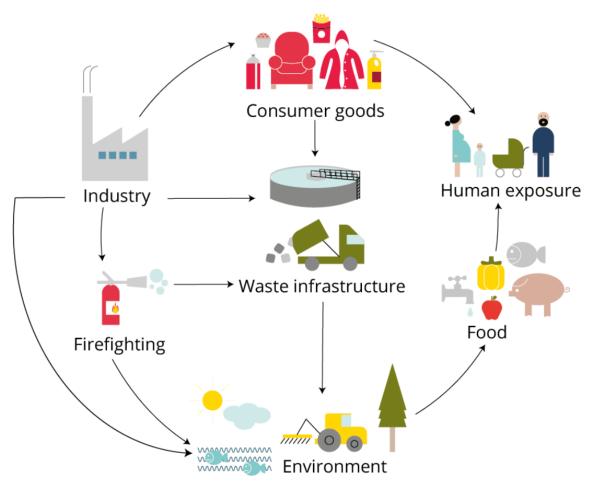


Figure Source: European Environment Agency. Briefing - Emerging chemical risks in Europe — 'PFAS' <u>https://www.eea.europa.eu/publications/emerging-chemical-risks-in-europe/emerging-chemical-risks-in-europe</u>

4. Potential Health Effects of PFAS Exposure

The potential risk of adverse effects following exposure to PFAS is dependent on several factors, including the exposure dose and frequency, the route and duration of exposure, and the time exposure occurs during the lifecycle (e.g., foetal development, early childhood) (8). Many studies have examined possible relationships between levels of PFAS in blood and harmful health effects in humans. However, these studies involved different PFAS, study populations, and exposure types. Therefore, the outcomes may not be directly comparable (6).

Scientific research involving humans suggests that high levels of certain PFAS may lead to particular health effects. However for most of these potential health effects, current scientific evidence is not clearcut or conclusive. These potential health effects include (6,18):

- Increased cholesterol levels
- Alterations in liver enzymes (elevated AST, ALT, GGT, ALP)

- Reduced immune response to vaccines in children
- Increased risk of high blood pressure and/or preeclampsia in pregnant women
- Small decreases in infant birth weights (<20 grams decrease per 1 ng/mL increase in blood PFOA or PFOS)
- Increased risk of kidney or testicular cancer

To see an overview the evidence from human studies regarding the potential health effects of PFAS exposure produced by the Agency for Toxic Substances and Disease Registry (ATSDR) in the United States, please see Appendix A (8).

According to the European Food Safety Authority (EFSA), there is currently not enough evidence to confirm several other suspected health effects of certain PFAS, such as diabetes and obesity, asthma and allergies, reduced kidney function and osteoporosis (4). Currently, investigations into the health effects of exposures to different PFAS are ongoing (6,19).

Due to the particular challenges of studying PFAS exposure and health, it can be difficult for scientists to reach robust and definitive conclusions with respect to health risks.

5. How can PFAS enter Drinking Water Supplies?

Ireland's raw water sources are our rivers, lakes, springs, and groundwater. PFAS are highly persistent and mobile in our environment and, as a result, if they make their way into our waterways they can travel some distances from where PFAS have been used and enter our drinking water supplies. PFAS can also travel from source areas in surface waters which may later contribute to drinking water supplies.

5.1 Can Drinking Water contaminated with PFAS be treated?

Water treatment technologies that have been shown to be capable of removing PFAS from drinking water include activated carbon filtration, reverse osmosis (RO), and anion exchange treatment. Carbon filtration has been demonstrated to be more effective for treatment of longer chain (more hydrophobic) PFAAs, such as PFOS and PFOA, as opposed to the shorter chain compounds such as PFHxA. Ion exchange resins are generally more successful in removing shorter chain anionic PFAS, as electrostatic interactions can be used to remove them from water (20).

6. Regulation of PFAS and Guideline Limits in Drinking Water

The European Union (EU) has undertaken several actions to reduce citizen exposure to PFAS, including (1,4):

- Two PFAS are currently restricted under the international *Stockholm Convention* on POPs (implying that parties to the Convention should 'eliminate the production and use' of the chemicals (2)) and the *EU POPs Regulation* (PFOS and its derivatives since 2009/2010, PFOA and its salts and related compounds, since 2020).
- Perfluorocarboxylic acids containing 9 to 14 carbon atoms in the chain (C9-C14 PFCAs), their salts and C9-C14 PFCA-related substances are banned under the *Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)*.
- Germany, Norway, Sweden, Denmark, and the Netherlands are proposing a ban on all PFAS, except for 'essential uses' under *REACH*. It is expected that this proposal will be submitted to the European Chemicals Agency (ECHA) by 15 July 2022.
- The European Food Safety Authority has defined a limit (TWI of 4.4 ng/kg bw) for the volume of four PFAS (PFHxS, PFOS, PFOA and PFNA) that may be safely consumed in food in a one-week period.
- The new EU Drinking Water Directive (EU 2020/2184) includes limits for total PFAS of 0.5 μg/L and the sum of 20 PFAS of most concern of 0.1 μg/L. The new Directive entered into force on 12th January 2021, with EU Member States having a 2-year transitional period to develop national laws, by 12th January 2023.
- The 2020 EU *Chemicals Strategy for Sustainability* sets out a range of actions to regulate PFAS as a group, including phasing out the use of PFAS in the EU, unless their use is deemed essential.

In general, regulated PFAS have been substituted with other short-chain and polymeric PFAS (2). Unfortunately, many of these 'novel' PFAS and their short chain degradation products are also persistent (2). In particular, short-chain PFAS accumulate in the environment and have been found to contaminate surface, ground- and drinking water (21–23), and accumulate in plants (24), which may result in increased human dietary exposure to PFAS (2).

Several European countries have been actively monitoring levels of PFAS in the environment as well as in humans and products (2). Some countries have set national limit values for water and soil (Denmark, Sweden, the Netherlands and Germany), for textiles (Norway) and for food contact materials (Denmark)(2). Moreover, drinking water limits for specific PFAS and for groups of PFAS have been set by many EU Member States (2,25). In June 2019, Denmark announced a ban on PFAS-treated food contact materials, which entered into force in 2020 (26).

In Ireland, the Environmental Protection Agency's (EPA) action plan on POPs includes several tasks relating to PFAS which are currently underway, including investigation of the extent of environmental contamination with PFAS (1). The EPA has also funded several research projects which have assessed the risks to human health posed by PFAS (1).

For further information on the regulatory context of PFAS in drinking water please see Appendix B.

7. Conclusion

PFAS are a very large group of synthetic chemicals that have been used in many industrial and consumer products since the 1950s. Most PFAS do not degrade and instead persist in the environment. Some PFAS can also bioaccumulate in people and animals over time.

Many scientific articles have been published about PFAS exposure and potential health effects. Some studies have shown that exposure to certain PFAS may be associated/linked with harmful health effects. Gaps remain in our knowledge of the health effects of PFAS and much research in this area is ongoing.

The new *EU Drinking Water Directive* (EU 2020/2184) will come into law in January 2023 and come into effect - with application of parametric values and monitoring requirements (including for PFAS), from January 2026.

8. Recommendations

In the context of the continuing emergence of new research findings on the potential health effects of PFAS exposure and the impending enactment of new legislation in accordance with the new *EU Drinking Water Directive*, the following is recommended:

- **Frequently Asked Questions (FAQs)** on PFAS and Drinking Water for general public (Interim FAQs were finalised by the HSE National Drinking Water Group in Dec2022)
- Joint position paper (HSE-EPA) on PFAS and Drinking Water
- HSE Guidance Document on PFAS Exceedances in Drinking Water
- Early review of this Interim Position Paper in the context of the continuing emergence of new evidence in the area of PFAS and human health

References

- Environmental Protection Agency. What are PFAS? [Internet]. 2022 [cited 2022 Apr 25]. Available from: https://www.epa.ie/our-services/monitoring-assessment/waste/chemicals/pfas/
- European Environment Agency. Briefing Emerging chemical risks in Europe 'PFAS' [Internet]. 2022 [cited 2022 Jun 16]. Available from: https://www.eea.europa.eu/publications/emerging-chemical-risks-ineurope/emerging-chemical-risks-in-europe
- 3. Glüge J, Scheringer M, Cousins IT, DeWitt JC, Goldenman G, Herzke D, et al. An overview of the uses of per-and polyfluoroalkyl substances (PFAS). Environ Sci Process Impacts. 2020;22(12):2345–73.
- 4. HBM4EU. Per- and Poly-Fluoroalkyl Substances (PFAS) What You Need To Know [Internet]. 2020. Available from: https://www.hbm4eu.eu/factsheets/pfas/
- 5. Fry K, Power MC. Persistent organic pollutants and mortality in the United States, NHANES 1999–2011. Environ Heal. 2017;16(1):1–12.
- U.S. Department of Health and Human Services ATSDR Agency for Toxic Substances and Disease Registry. Per- and Polyfluoroalkyl Substances (PFAS): A Short Review and Guidance for Clinicians [Internet]. 2020. Available from: https://www.atsdr.cdc.gov/pfas/docs/PFAS-Short-Review-508.pdf
- European Chemicals Agency (ECHA). Perfluoroalkyl chemicals (PFAS) [Internet]. 2022 [cited 2022 May 5]. Available from: https://echa.europa.eu/hot-topics/perfluoroalkylchemicals-pfas
- ATSDR Agency for Toxic Substances and Disease Registry. PFAS An Overview of the Science and Guidance for Clinicians on Per- and Polyfluoroalkyl Substances (PFAS) [Internet]. 2019. Available from: https://www.atsdr.cdc.gov/pfas/docs/clinicalguidance-12-20-2019.pdf
- Centers for Disease Control and Prevention National Biomonitoring Program. Perand Polyfluorinated Substances (PFAS) Factsheet [Internet]. 2022 [cited 2022 May 5]. Available from: https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html
- ATSDR Agency for Toxic Substances and Disease Registry. Per- and Polyfluoroalkyl Substances (PFAS) and Your Health - How can I be exposed? [Internet]. 2021 [cited 2022 May 5]. Available from: https://www.atsdr.cdc.gov/pfas/healtheffects/exposure.html
- HBM4EU. Scoping documents for 2021 for the first and second second round HBM4EU priority substances, Deliverable Report D4.9 [Internet]. 2020. Available from: https://www.hbm4eu.eu/wpcontent/uploads/2021/03/HBM4EU_D4.9_Scoping_Documents_HBM4EU_priority_su bstances_v1.0.pdf
- 12. United States Nuclear Regulatory Commission Glossary. U.S. NRC Glossary Biological

half-life [Internet]. 2021 [cited 2022 Jun 15]. Available from: https://www.nrc.gov/reading-rm/basic-ref/glossary/biological-half-life.html

- 13. Harada K, Inoue K, Morikawa A, Yoshinaga T, Saito N, Koizumi A. Renal clearance of perfluorooctane sulfonate and perfluorooctanoate in humans and their species-specific excretion. Environ Res. 2005;99(2):253–61.
- 14. Li Y, Fletcher T, Mucs D, Scott K, Lindh CH, Tallving P, et al. Half-lives of PFOS, PFHxS and PFOA after end of exposure to contaminated drinking water. Occup Environ Med. 2018;75(1):46–51.
- 15. Olsen GW, Burris JM, Ehresman DJ, Froehlich JW, Seacat AM, Butenhoff JL, et al. Halflife of serum elimination of perfluorooctanesulfonate, perfluorohexanesulfonate, and perfluorooctanoate in retired fluorochemical production workers. Environ Health Perspect. 2007;115(9):1298–305.
- 16. Worley RR, Moore SM, Tierney BC, Ye X, Calafat AM, Campbell S, et al. Per-and polyfluoroalkyl substances in human serum and urine samples from a residentially exposed community. Environ Int. 2017;106:135–43.
- 17. Zhang Y, Beesoon S, Zhu L, Martin JW. Biomonitoring of perfluoroalkyl acids in human urine and estimates of biological half-life. Environ Sci Technol. 2013;47(18):10619–27.
- 18. ATSDR Agency for Toxic Substances and Disease Registry. Talking to Your Doctor about Exposure to PFAS [Internet]. 2022 [cited 2022 May 5]. Available from: https://www.atsdr.cdc.gov/pfas/health-effects/talk-to-your-doctor.html
- ATSDR Agency for Toxic Substances and Disease Registry. Per- and Polyfluoroalkyl Substances (PFAS) and Your Health - Health Studies [Internet]. 2020 [cited 2022 Jun 24]. Available from: https://www.atsdr.cdc.gov/pfas/activities/studies.html
- Ross I, Hall O. What's the Pfuss all about? Pragmatic PFAS Management Options. In: Groundwater: Making the Invisible Visible - the 42nd Annual Groundwater Conference [Internet]. 2022. Available from: https://www.iahireland.org/conference-proceedings/2022.pdf
- 21. Eschauzier C, Beerendonk E, Scholte-Veenendaal P, De Voogt P. Impact of treatment processes on the removal of perfluoroalkyl acids from the drinking water production chain. Environ Sci Technol. 2012;46(3):1708–15.
- Sun M, Arevalo E, Strynar M, Lindstrom A, Richardson M, Kearns B, et al. Legacy and emerging perfluoroalkyl substances are important drinking water contaminants in the Cape Fear River Watershed of North Carolina. Environ Sci Technol Lett. 2016;3(12):415–9.
- 23. Gebbink WA, Van Asseldonk L, Van Leeuwen SPJ. Presence of emerging per-and polyfluoroalkyl substances (PFASs) in river and drinking water near a fluorochemical production plant in the Netherlands. Environ Sci Technol. 2017;51(19):11057–65.
- 24. Ghisi R, Vamerali T, Manzetti S. Accumulation of perfluorinated alkyl substances (PFAS) in agricultural plants: A review. Environ Res. 2019;169:326–41.
- 25. Dauchy X. Per-and polyfluoroalkyl substances (PFASs) in drinking water: current state

of the science. Curr Opin Environ Sci Heal. 2019;7:8–12.

26. Keller and Heckman LLP. Denmark's PFAS Ban in Paper and Cardboard Effective in July 2020 [Internet]. 2020 [cited 2022 Jun 16]. Available from: https://www.packaginglaw.com/news/denmarks-pfas-ban-paper-and-cardboardeffective-july-2020

Appendix A :

Table Source: Table 1 in 'U.S. *Agency for Toxic Substances and Disease Registry (ATSDR).* An Overview of the Science and Guidance for Clinicians PFAS on Per- and Polyfluoroalkyl Substances (PFAS) 2019'.

Health Effect	Evidence
Cholesterol	Several epidemiological studies report statistically significant associations between serum PFOA and PFOS concentrations and total cholesterol in: 1) workers exposed to PFAS, and 2) residents of communities with high levels of PFOA in their drinking water. However, the associations between cholesterol levels and PFAS exposure are not consistent among human studies and no causal relationship has been established.
Uric Acid	Several epidemiological studies report positive associations between serum PFOA and PFOS concentrations and serum uric acid concentrations in residential community and occupational populations, but reverse causality may be applicable, and no causal relationship has been established.
Liver Effects	Several epidemiological studies report a positive association between serum PFOA concentration and liver enzymes (AST, ALT, GGT, ALP) and an inverse association between serum PFOA and bilirubin level in occupational and residential community populations. However, the associations between liver enzymes and PFAS exposure are not consistent among human studies and no causal relationship has been established.
Kidney Effects	Several epidemiological studies on occupational, general, and community populations report an association between exposure to PFAS and reduced kidney function, cellular and histological derangements in proximal tubules of the nephron, and dysregulated metabolic pathways. Variations in these effects are reported based on the specific PFAS and/or the age, sex, ethnicity, and medical history of the individual. However, there is a lack of strong evidence to definitively establish a causal relationship.
Endocrine Disruptors	Several epidemiological studies on occupational, general, and community populations report prenatal exposure to PFAS, in particular PFOS and PFOA, is associated with increased body fat, increased risk of cardio-metabolic disorders, and obesity during childhood and adulthood. However, these associations are not consistent among human studies and no causal relationship has been established.
Thyroid Effects	General population and occupational studies report an association between serum PFOA and increased risk of thyroid disease. There may also be an association between serum PFOS and thyroid disease. Other studies report an association between serum PFOA and PFOS and thyroid stimulating hormone (TSH), triiodothyronine (T3), or thyroxine (T4) levels. However, these associations are not consistent among human studies and no causal relationship has been established.
Immune effects	The National Toxicology Program (NTP) conducted a systematic review of the human, animal, and in vitro data examining immunotoxic effects of PFOA and PFOS. They concluded that both PFOA and PFOS are "presumed to be immune hazards to humans." Evidence was considered strong that both compounds were associated with decreased antibody response to vaccines, while there was weaker evidence for PFOA-induced impairment of infectious disease resistance, and increased hypersensitivity-related outcomes. The NTP is

Table 1. Over	view of Humar	Studies
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	undertaking additional systematic reviews to evaluate immunotoxicity of six other related PFAS.
Ulcerative Colitis	Limited epidemiological studies have investigated the relationship between ulcerative colitis and PFAS. Few studies report a positive association with PFOA and ulcerative colitis. However, this is not consistent in the literature, reverse causality may be applicable, and no causal relationship has been established.
Asthma	Few general population and occupational studies have investigated a relationship with asthma. Some of these studies report a positive association between several serum PFAS and asthma. However, these associations are not consistent among children in varying age ranges and no causal relationship has been established. Population studies have not found an association between PFAS exposure and atopic eczema, allergic rhinitis, food allergy, and pollen allergy.
Neuro- behavioural	Few studies address neurobehavioral changes in children (e.g., ADHD, autism, hyperactivity) and PFAS exposure. Variations of neurobehavioral changes are reported based on the specific PFAS, child age and sex. However, these associations are not consistent among human studies and no causal relationship has been established. Learning problems and PFAS exposure have also been studied in children but there is weak evidence to support health endpoints. ATSDR and partners are conducting further investigations into neurobehavioral and learning health effects.
Reproductive Health	A few epidemiological studies report an association between PFAS exposure in women and lower fertility and fecundity. However, the associations are not consistent among human studies, especially in relation to parity, and no causal relationship has been established. In men, a few studies have shown a weak association between PFAS exposure and semen quality or levels of productive hormones, however, no causal relationship has been established for these findings.
Preeclampsia	Few epidemiological studies have investigated the relationship between preeclampsia and PFAS. Early general population studies 9-17 reported a possible association between serum PFOA exposure and preeclampsia.13 However, these associations are not consistent among all pregnant women and no causal relationship has been established.
Birth weight	Several epidemiological studies report a possible association between elevated maternal blood and fetal cord blood PFAS concentrations (primarily PFOS and PFOA) and decreased birth weight. However, the association between the maternal PFAS level and decreased birth weight did not consistently show statistical significance. Further, the observed reduction in birth weight does not consistently equate with increased risk of a low birth weight (LBW) infant.
Cancer	The International Agency for Research on Cancer (IARC) has classified PFOA as possibly carcinogenic to humans (Group 2B), and EPA has concluded that evidence suggests carcinogenic potential for both PFOA and PFOS in humans. Some studies report increases in prostate, kidney, and testicular cancers in workers exposed to PFAS and people living near a PFOA facility. Other studies have not found increases in cancer. However, these associations are not consistent among human studies and no causal relationship has been established.

Appendix B :

REGULATORY CONTEXT OF PER- AND POLYFLUOROALKYL SUBSTANCES (PFAs) IN DRINKING WATER

BACKGROUND

Legislation to control and limit production of Per- and polyfluoroalkyl Substances (PFAs) has come into effect both within the European Union and internationally over the last decade. Perfluorooctanoic acid (PFOA) in drinking water was recently set at 0.002 μ g/l in Illinois (1) whilst in Denmark a 0.002 μ g/l level has been set for the sum of PFOA, perfluorooctane sulphonic acid (PFOS), perfluorohexanesulphonic acid (PFHxS) and perfluorononanoic acid (PFNA) in drinking water (2). In the US the EPA developed a PFAs strategic roadmap (3) which, amongst many other actions requires the EPA to set enforceable drinking water limits for certain PFAs under the Safe Drinking Water Act by late 2022 and by the early 2022, draft a proposed rule designating certain PFAS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). In the UK in late 2021, the UK drinking inspectorate instructed water companies to assess every raw drinking water abstraction for some 47 different PFAS (4) following announcement of new lower drinking water standards for PFOS and PFOA (at 0.1 μ g/l).

The European Union (EU) has undertaken several actions to reduce citizen exposure to PFAs, including:

- Two PFAS are currently restricted under the international *Stockholm Convention* on POPs and the *EU POPs Regulation* (PFOS and its derivatives since 2009/2010, PFOA and its salts and related compounds, since 2020)
- Perfluorocarboxylic acids containing 9 to 14 carbon atoms in the chain (C9-C14 PFCAs), their salts and C9-C14 PFCA-related substances are banned under the *Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)*.
- Germany, Norway, Sweden, Denmark, and the Netherlands are proposing a ban on all PFAS, except for 'essential uses' under *REACH*. It is expected that this proposal will be submitted to the European Chemicals Agency (ECHA) by 15 July 2022.
- The European Food Safety Authority has defined a limit (TWI of 4.4 ng/kg bw) for the volume of four PFAS (PFHxS, PFOS, PFOA and PFNA) that may be safely consumed in food in a one-week period.
- The 2020 EU *Chemicals Strategy for Sustainability* sets out a range of actions to regulate PFAS as a group, including phasing out the use of PFAS in the EU, unless their use is deemed essential.
- The new EU Drinking Water Directive (EU 2020/2184) includes limits for total PFAS of 0.5 μg/L and the sum of 20 PFAS of most concern of 0.1 μg/L. The new Directive

entered into force on 12th January 2021, with EU Member States having a 2-year transitional period to develop national laws, by 12th January 2023.

IRISH DRINKING WATER REGULATION

Current legislation relating to the safety and quality of Irish drinking water derives principally from Council Directive 98/83/EC on the quality of water intended for human consumption (transposed via Irish regulation S.I. 144 of 2014). Commission Directive 2015/1787 (transposed via Irish regulation S.I. 464 of 2017) updated the monitoring requirements set out in Directive 98/83. From 12th January 2023 the above legislation will be replaced by Directive (EU) 2020/2184 on the quality of water intended for human consumption (recast).

MONITORING OF SUPPLY TYPES UNDER IRISH REGULATION

Under current legislation, Irish Water has responsibility for all public water supplies with the EPA acting as supervisory authority. Private suppliers (i.e. private group water schemes, private commercial suppliers and where water is supplied to the public or as part of a commercial activity) are responsible for relevant monitoring of their supplies. (5) Local Authorities are the supervisory authority in relation to such private supplies. The EPA can supervise the performance of Local Authorities' monitoring functions under the EU Regulations [Regulation 7(12)]. (5)

Individual or small private supplies are exempt* from legislative supervision. However, Local Authorities are responsible for notifying the population served by an exempted supply of the fact that the regulations do not apply to such supply and of actions that can be taken to protect human health from any water contamination [Regulation 14(1)]. (5)

*Exempted Supply is a supply of water which constitutes an individual supply of less than 10 cubic metres a day on average or serves fewer than 50 persons, and is not supplied as part of a commercial or public activity

MONITORING OF PFAS UNDER NEW EU DRINKING WATER DIRECTIVE (EU 2020/2184)

The new Directive retains the more flexible risk-based approach of Directive 2015/1787 with regard to parameters to be monitored. Monitoring programmes must be supply-specific, taking into account the catchment and supply risk assessments under articles 8 and 9.

It incorporates the same **'Group A'** list of parameters introduced by Directive 2015/1778, with the addition of: **Intestinal Enterococci**. The **'Group B'** list is, essentially, everything else (meaning, of course, that it also includes the new parameters contained in Dir. 2020/2184 such as PFAs). The new chemical parameters including PFAs do not have to be monitored until January 2026.

MONITORING FREQUENCIES:

Minimum monitoring frequencies for Group A & Group B parameters, as with previous Directive, are based on volume of water distributed and are set out in Annex II part B (2) Table 1.

Monitoring frequencies (and range of parameters tested) may be **increased** where a risk assessment suggests there is a need to do so (Annex II part C (1)).

Monitoring frequencies and range of parameters tested, except in case of E. coli & Intestinal Enterococci, may be **reduced** on basis of risk assessment (Annex II part C (2)) e.g. where representative samples over at least 3 years show parametric value never exceeding 60% of parametric value, monitoring frequency for that parameter can be reduced.

Where, over a similar sampling programme, results never exceed 30% of parametric value, that parameter can be dropped from sampling programme. Results from samples taken before January 2021 can be taken into account as part of the above flexibility option.

As mentioned previously the new *EU Drinking Water Directive* (EU 2020/2184) includes limits for total PFAS of 0.5 μ g/L and the sum of 20 PFAS of most concern of 0.1 μ g/L.

PFAs Total (The totality of per- and polyfluoralkyl substances): Parameter value = $0.5 \mu g/l$

By 12 January 2024, the Commission shall establish technical guidelines regarding methods of analysis for monitoring of per- and polyfluoroalkyl substances under the parameters 'PFAS Total' and 'Sum of PFAS', including detection limits, parametric values and frequency of sampling.

Member State can opt to use either 'PFAs Total' or 'Sum of PFAs' parameter or both

Parametric values and monitoring requirements only then apply to new parameters (including PFAs) from January 2026 (see Article 25)

Sum of PFAs: Parameter value: 0.1 µg/l

The new Directive (EU 2020/2184) lists 20 PFAs of most concern. The following substances shall be analysed based on the technical guidelines developed in accordance with Article 13(7):

- 1) Perfluorobutanoic acid (PFBA)
- 2) Perfluoropentanoic acid (PFPA)
- 3) Perfluorohexanoic acid (PFHxA)
- 4) Perfluoroheptanoic acid (PFHpA)
- 5) Perfluorooctanoic acid (PFOA)
- 6) Perfluorononanoic acid (PFNA)
- 7) Perfluorodecanoic acid (PFDA)

- 8) Perfluoroundecanoic acid (PFUnDA)
- 9) Perfluorododecanoic acid (PFDoDA)
- 10) Perfluorotridecanoic acid (PFTrDA)
- 11) Perfluorobutane sulfonic acid (PFBS)
- 12) Perfluoropentane sulfonic acid (PFPS)
- 13) Perfluorohexane sulfonic acid (PFHxS)
- 14) Perfluoroheptane sulfonic acid (PFHpS)
- 15) Perfluorooctane sulfonic acid (PFOS)
- 16) Perfluorononane sulfonic acid (PFNS)
- 17) Perfluorodecane sulfonic acid (PFDS)
- 18) Perfluoroundecane sulfonic acid
- 19) Perfluorododecane sulfonic acid
- 20) Perfluorotridecane sulfonic acid

Those substances shall be monitored when the risk assessment and risk management of the catchment areas for abstraction points carried out in accordance with Article 8 conclude that those substances are likely to be present in a given water supply.

REFERENCES

- Health, I.D.o.P. *PFAS in Drinking Water*. 2021; Available from: https://dph.illinois.gov/topics-services/environmental-healthprotection/privatewater/ fact-sheets/pfas-drinking-water.html.
- 2. DHI. Danish EPA more tough on PFAS in drinking water. 2021; Available from: https://tox.dhi.dk/en/news/news/article/danish-epa-more-tough-on-pfas-indrinkingwater/.
- USEPA. PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024. 2021; Available from: https://www.epa.gov/system/files/documents/2021-10/pfasroadmap_ final-508.pdf.
- DWI. Requirements for Poly and Perfluorinated Alkyl Substances (PFAS) monitoring by water companies in England and Wales. 2021; Available from: <u>https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf</u>.
- 5. European Union (Drinking Water) Regulations 2014 (S.I. No. 122 of 2014). The Stationery Office: Dublin.