Emerging risks of chemicals in Europe – an example of 'PFAS'

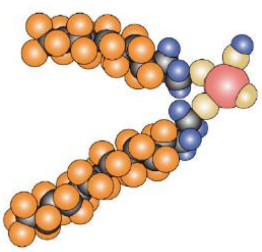
- *Comprising more than 4 700 chemicals, per and polyfluorinated alkyl substances (PFAS) are a group of widely-used man-made chemicals which accumulate over time in humans and in the environment. The two most studied and prevalent chemicals are PFOA and PFOS.*
- *Monitoring activities at National level have detected PFAS in the environment across Europe.*
- *The production and use of the PFAS has resulted in the contamination of drinking water supplies in several European countries, leading directly to human exposure.*
- *In human biomonitoring studies conducted in Belgium, Denmark and Slovakia, PFOA and PFOS were found in the blood of all citizens, with average concentrations ranging from 4-55%, and for the highly exposed population 11-140% of the provisional safe levels in humans set by the European Food Safety Authority (*EFSA 2018*).*
- *Knowledge is lacking of the properties and potential risks posed most other PFAS and mixtures thereof.*
- *A substance-by-substance approach to risk assessment and management is not adequate to efficiently address the large number of PFAS.*
- *Improved knowledge and complementary approaches in chemicals regulation, including grouping of substances, consideration of mixtures, essential uses and chemicals that are 'safe-and-circular-by-design', could help limit further pollution of people, products and the environment.*

The great variety and volumes of chemicals used in Europe means that it is presently impossible to perform in-depth environmental and health risk assessments of all substances. New and legacy chemicals continue to be released into Europe's environment, adding to the total chemical burden on Europe's citizens and ecosystems. Early identification of emerging risks is one of the environmental issues that the European Environment Agency (EEA) helps address. This briefing summarises the known and potential risks to human health and the environment in Europe posed by a group of very persistent chemicals, the per- and polyfluorinated alkyl substances (PFAS).

What are PFAS and what are they used for?

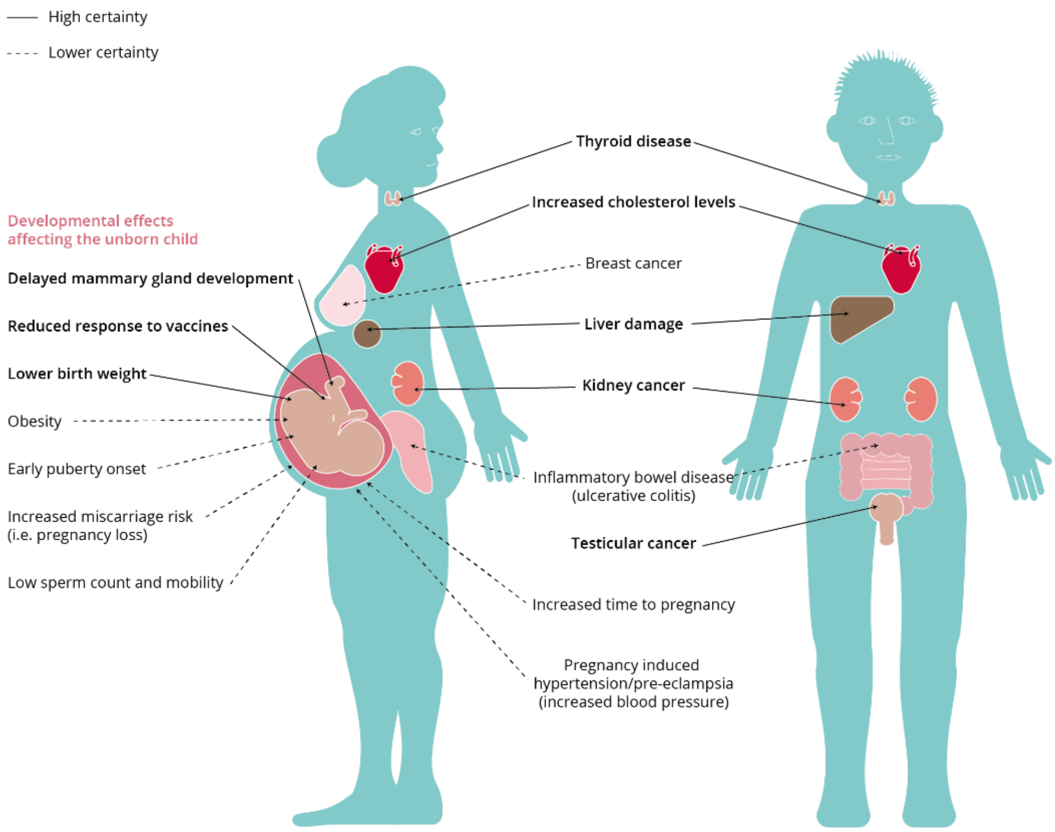
PFAS are a group of more than 4 700 man-made chemicals (OECD 2018), with the two most well-known substances being *perfluorooctanoic acid* (PFOA) and *perfluorooctane sulfonic acid* (PFOS) (Box 1). PFAS are used in a wide variety of consumer products and industrial applications, due to their unique chemical and physical properties including oil and water repellence, temperature and chemical resistance, and surfactant properties. PFAS are used in firefighting foams, fluoropolymers such as Teflon™ and Goretex®, paper food packaging, non-stick kitchen utensils, creams and cosmetics, textiles for furniture and outdoor clothing, paints and photography, chrome plating, pesticides and pharmaceuticals. Very limited information is available regarding which PFAS are used in which applications and at what levels.

Box 1: PFAS is a group of organic chemicals, which contains a stable (unreactive) fluoro-carbon segment. *Polyfluorinated* PFAS contain both fluoro-carbon and hydro-carbon segments, where the non-fluorinated part can degrade and ultimately form *perfluorinated* PFAS acids, such as PFOA and PFOS. While the *long-chain* PFAS accumulate in humans, animals and sediment/soil, the *short-chain* PFAS are mobile in the environment, and can be transported and accumulate in air and water. For information on groups of PFAS see OECD 2018. The picture shows a poly-fluorinated PFAS (polyfluoroalkyl phosphoric acid diester, diPAPs), with fluorine atoms (orange) and hydrogen atoms (blue), attached to two carbon chains(grey), connected by a polar phosphate acid group.



Why are PFAS a concern? PFAS degrade to persistent chemicals, which can accumulate in humans, animals and in the environment. This adds to the total burden of chemicals to which people are exposed and increases the risk of health impacts. Of the relatively few well-studied PFAS, most of them are considered moderately to highly toxic, particularly for the development of children Figure 1 summarises current knowledge on the health impacts of PFAS.

Figure 1. Effects of PFAS on human health



Sources: EEA, primarily based on the toxicological profile for perfluoroalkyls (US ASTDR 2018); the US Monograph on Immunotoxicity (National Toxicology Program, 2016), Cancer studies (C8 Health Project Reports 2012, IARC 2017 , Barry, 2013), and developmental effects (Fenton 2009, White 2011).

People exposed to the highest levels of PFAS are most at risk of health impacts, while fewer studies have investigated effects on biota (Land 2018). Throughout life people and animals accumulate PFAS in their bodies, adding to the vulnerability of particularly children and the elderly. In 2018, the European Food Safety Authority (EFSA) re-evaluated the multiple lines of evidence of PFOA and PFOS toxicities, which resulted in significantly lower provisional 'safe' limits, known as 'tolerable weekly intake' (TWI) (EFSA 2018). The assessment concluded that a substantial part of the European population is expected to exceed the limits, due to PFAS intake from food and drinking water.

Costs to society arising from PFAS exposure are high, which the annual health-related costs estimated as 52 – 84 billion EUR across Europe in a recent Nordic study. These costs are likely underestimated, as only a limited range of health effects (high cholesterol, decreased immune system and cancer) linked to exposure to a few PFAS were included in the estimates. In addition, PFAS pollution also affect ecosystems and generates costs through the subsequent need for remediation of polluted soil and water. Such costs are currently difficult to assess, since an overview of PFAS-contaminated sites and knowledge on how PFAS impacts various ecosystems are both lacking.

What are the main sources of environmental PFAS pollution?

- *The production and use of PFAS* have been the main sources of PFAS contamination over time (Wang 2014a, 2014b, Hu 2016), for instance from fluoropolymer production such as Teflon™ and from training and fire-extinguishing with PFAS-containing firefighting foams (Figure 1). This has resulted in serious contamination of drinking water around factories in the Netherlands, Belgium and Italy, and around airports and military bases in Sweden, Germany and the UK (IPEN 2018, Hu 2016). Other sources include PFAS produced and applied to textiles and paper and painting/printing facilities (Danish EPA 2016). Less is known about emissions of other PFAS used in e.g. pharmaceuticals, pesticides or for mining/oil extraction.
- *PFAS in products* such as textiles, furniture, polishing, cleaning agent and creams may contaminate dust and air, while food contact materials may contaminate food (NCM 2018, Danish EPA 2018)
- *Emissions to the environment* occur via industrial wastewater releases, as well as leaching from contaminated soils and emissions to air from industrial production sites followed by deposition onto soil and water bodies. Urban wastewater treatment plants are also a significant source of PFAS, via air, water and sludge.
- *The reuse* of contaminated sewage sludge as fertilisers has led to the pollution of soil and water with PFAS in Germany, Austria, Switzerland and the US (Ghisi 2019, NCM 2019). The recycling of PFAS containing materials, such as food contact materials, and the formation of volatile fluorinated gases during waste incineration are other possible sources of PFAS pollution.

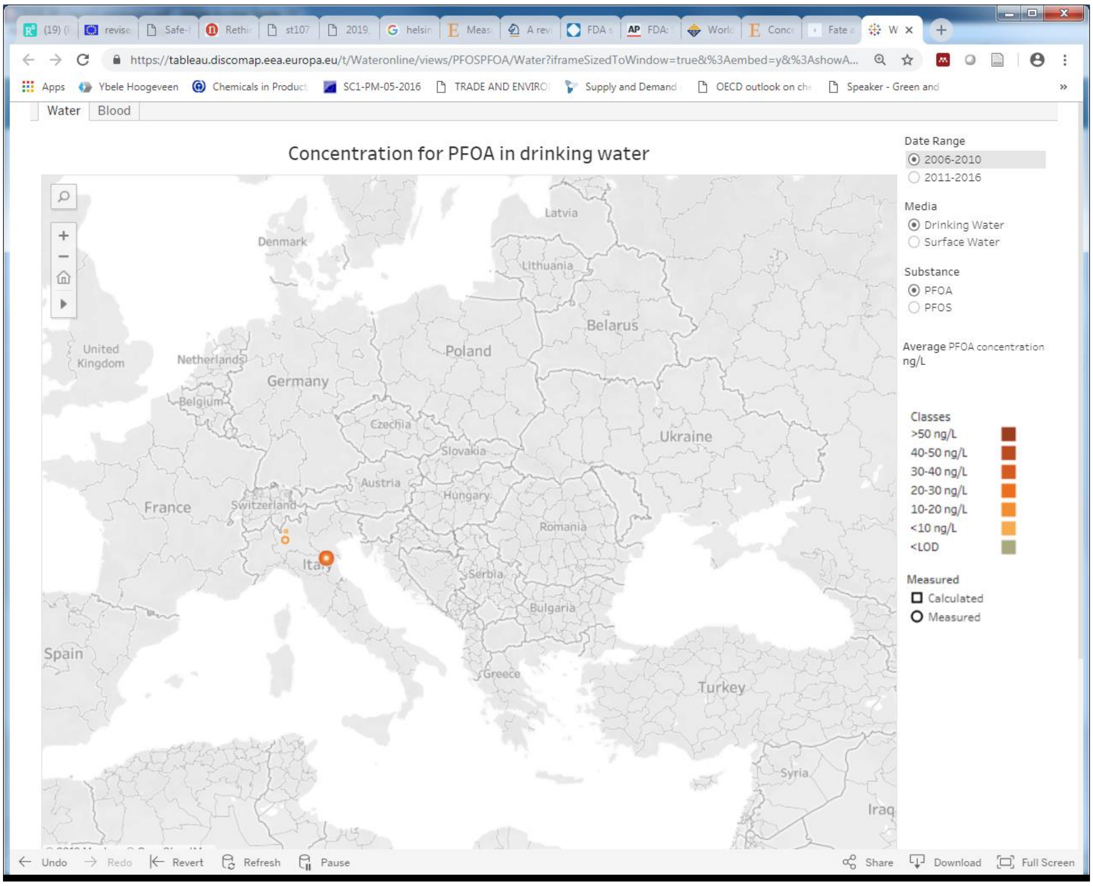
PFAS contamination is difficult, costly and often impossible to remediate, and may even create other and more mobile and persistent PFAS upon forced degradation. Often the pollution is irreversible and economically impossible to clean up in soil, air, or water (Dauchy 2019, NCM 2019).

Where are PFAS found in Europe's environment?

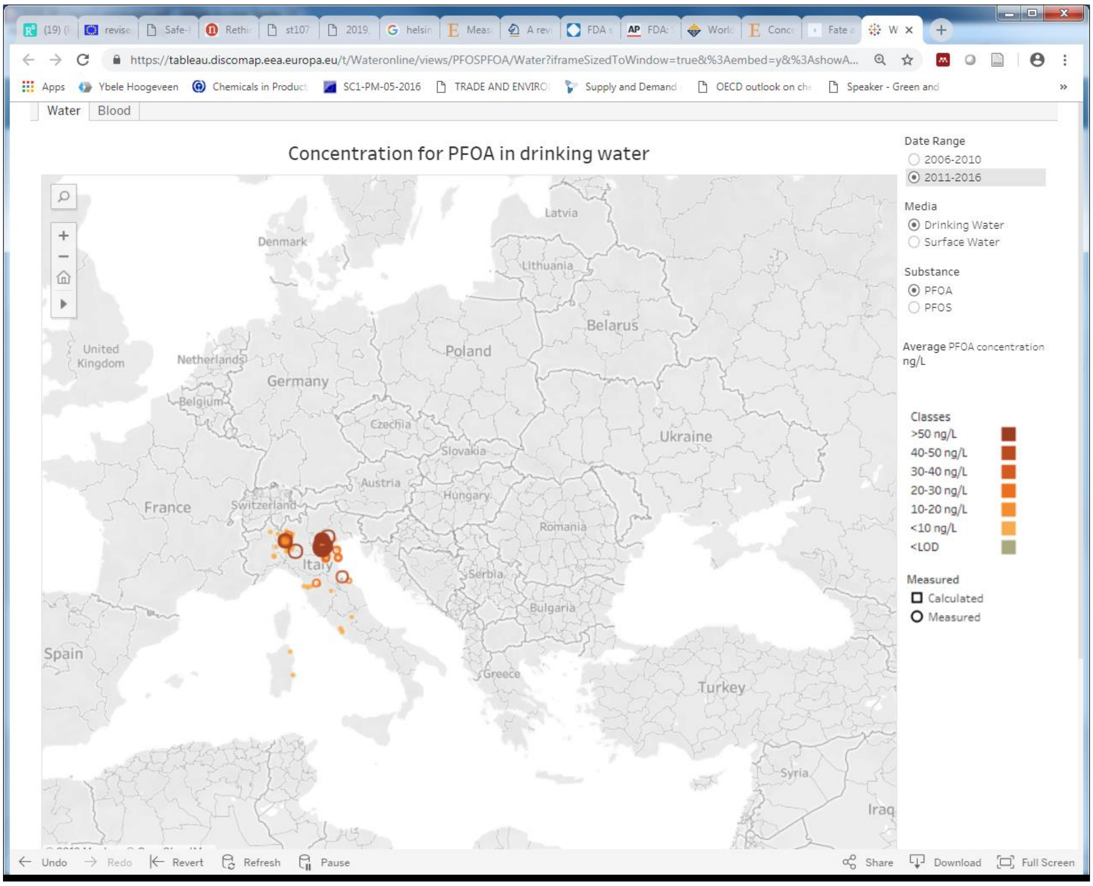
PFAS ubiquitous in the aquatic environment and organisms across Europe, and have been detected widely in air, soil, plants and biota (Babut 2017). Areas around industrial production and application sites, airports and military bases tend to be particularly contaminated by PFAS, with the total number of sites potentially emitting PFAS estimated to be in the order of 100,000 or greater in Europe. Novel PFAS are increasingly being detected in European surface waters, and particularly near PFAS producing areas, of which many are situated in Asia. Several PFAS are sufficiently volatile to be long-range transboundary air pollutants, implying that emissions outside Europe are transported into Europe, where they particularly accumulate in cold areas such as the Arctic (EEA 2017). The well-known PFAS account only for a fraction of the total organic fluorine present in human blood, the environment and wildlife.

Well-known and new types of PFAS have been detected in drinking water (Xiao 2017, Kaboré 2018, Dauchy 2019). At present publically available monitoring data is limited in the EU. However, drinking water data is available from 21 municipalities in the Veneto region in Italy, where industrial activity has polluted the ground, surface and drinking water of approximately 127 000 citizens (WHO, 2017). Data from PFOA and PFAS in drinking water in the Veneto region of Italy for the years 2006-2010 and 2011-2016 is presented in maps 1 and 2 below.

Map 1 – PFOA in drinking water, 2006-2010

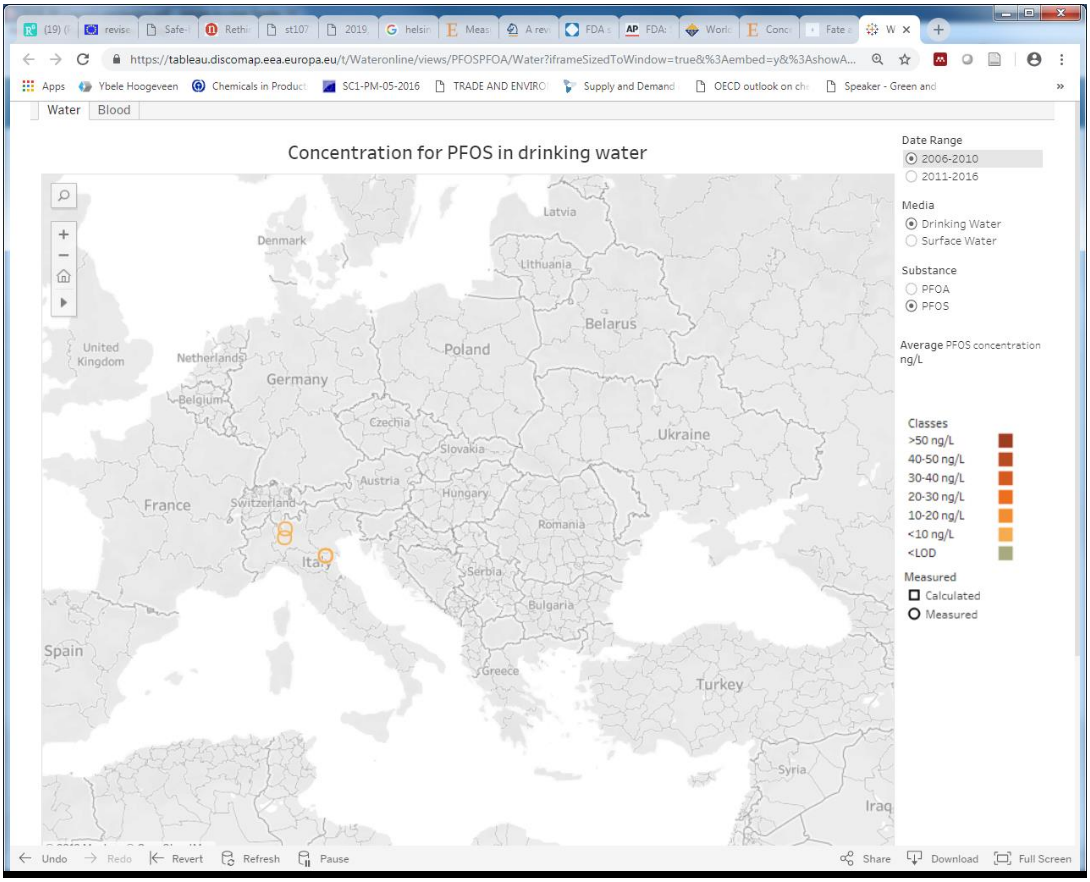


Map 2 – PFOA in drinking water, 2011-2016

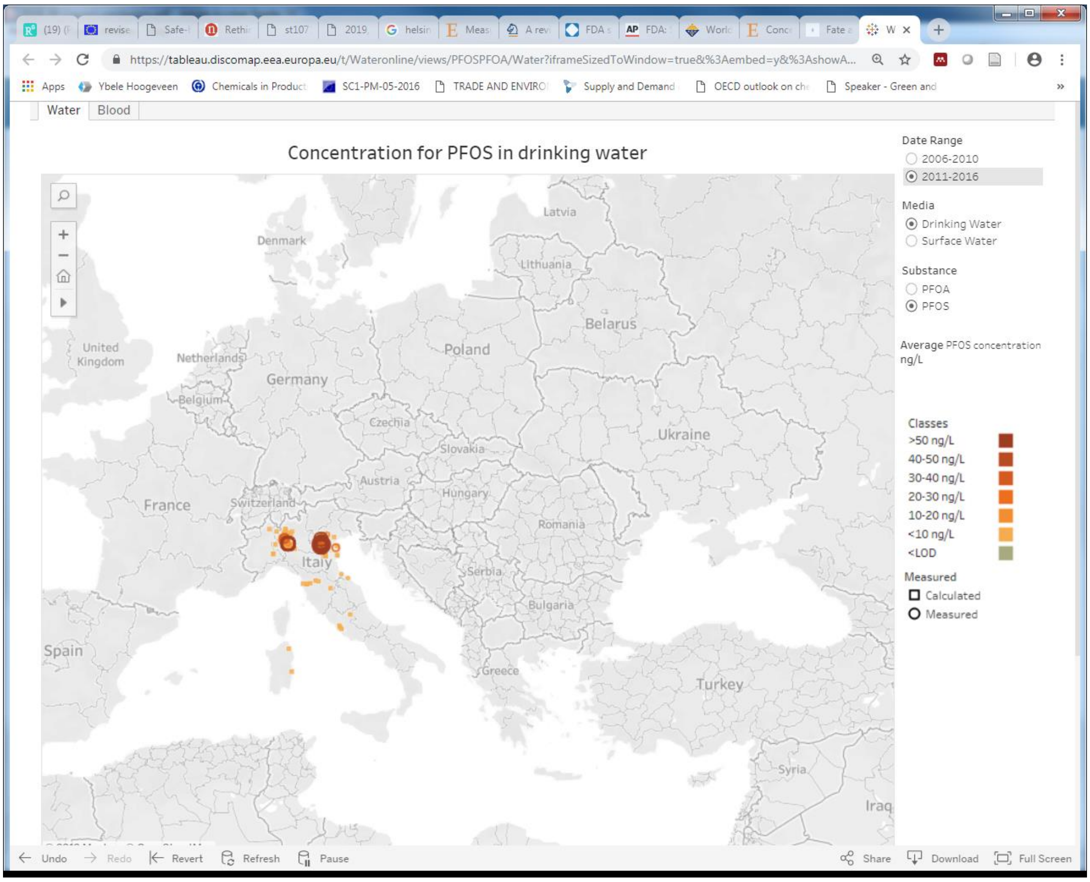


Source: IRSA-CNR: Perfluoroalkyl acids in Italy

Map 2 – PFOS in drinking water, 2006-2010



PFOS in drinking water, 2011-2016



Source: [IRSA-CNR: Perfluoroalkyl acids in Italy]

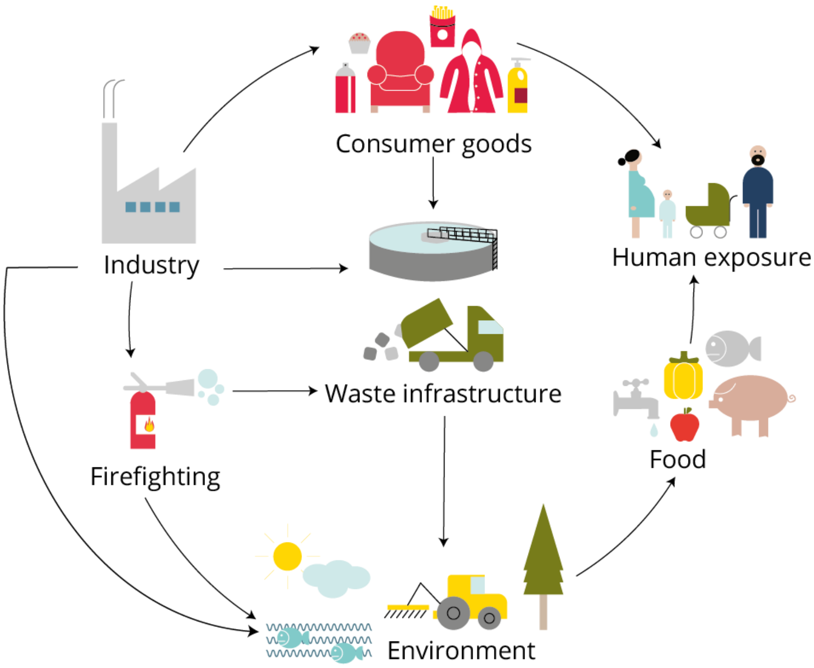
Upon discovery, in 2013 the Veneto Region set up an intersectoral group that undertook a series of precautionary actions, and installed water filters to reduce the PFAS levels in the drinking water. In the period 2006-2016 PFOS was found in 63-100% of the locations (median 6.6 µg/L, range 2.5 – 40 µg/L, n=44), and PFOA in 100% of the sites (median 13 µg/L, range 2.1 – 195 µg/L, n=52). Compared with the proposed EU drinking water limit value of 0.1 µg/L (i.e. 100 ng/L) for each of the 16 listed PFAS including PFOA and PFOS, the average levels were exceeded by a factor 130 for PFOS, and 66 for PFOA. Several EU member states have drinking water limits for specific and groups of PFAS (Dauchy 2019).

For comparison, PFOS and its derivatives is currently included on the EU Surface Water Watch List, with a much lower Environmental Quality Standard (AA-EQS) limit of 0.00065 µg/L (0.65 ng/L) in inland surface waters and 0.13 ng/L in seawater. By 2024, Member States will be due to report on compliance with the PFOS EQS. Samples taken in 2013 in Northern Europe had exceedances of 25% in inland surface water and in 94% of seawater (Nguyen 2017).

What are the main routes of human exposure to PFAS?

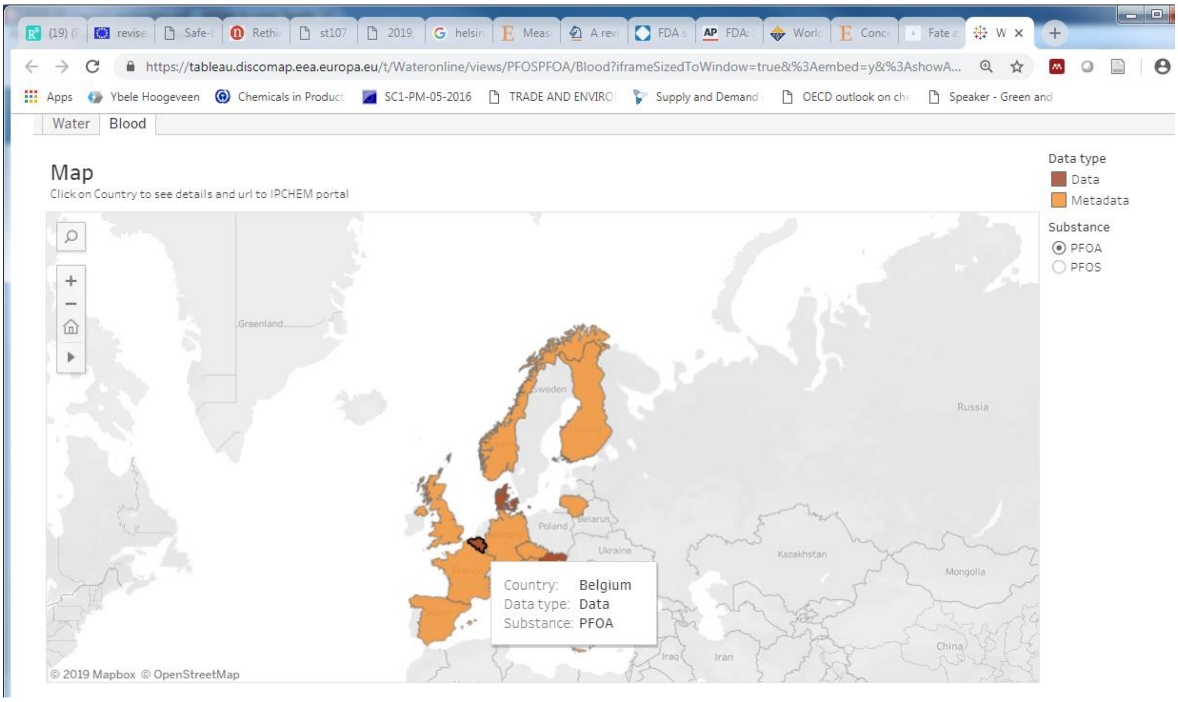
The main exposure pathways for human and environmental exposures are shown in Figure 2. For the general population, these include drinking water, food, consumer products and dust (EFSA 2018). In food, fish species at the top of the food chain may be particularly contaminated due to bioaccumulation. Cattle, hens and pigs fed on feed grown on contaminated soil, can accumulate PFAS in the meat, milk and eggs. Direct exposure may also come via creams and cosmetics (Danish EPA 2018, Schultes 2018), or via air from sprays and dust from PFAS-coated textiles. There is little knowledge on uptake via skin and the lungs. Consumer exposure may occur via oil repellent food contact materials and floor and car cleaning and polishing products. Groups that may be exposed to high concentrations of PFAS include workers producing or applying PFAS and people drinking contaminated water or eating contaminated foods.

Figure 2: Typical PFAS exposure pathways

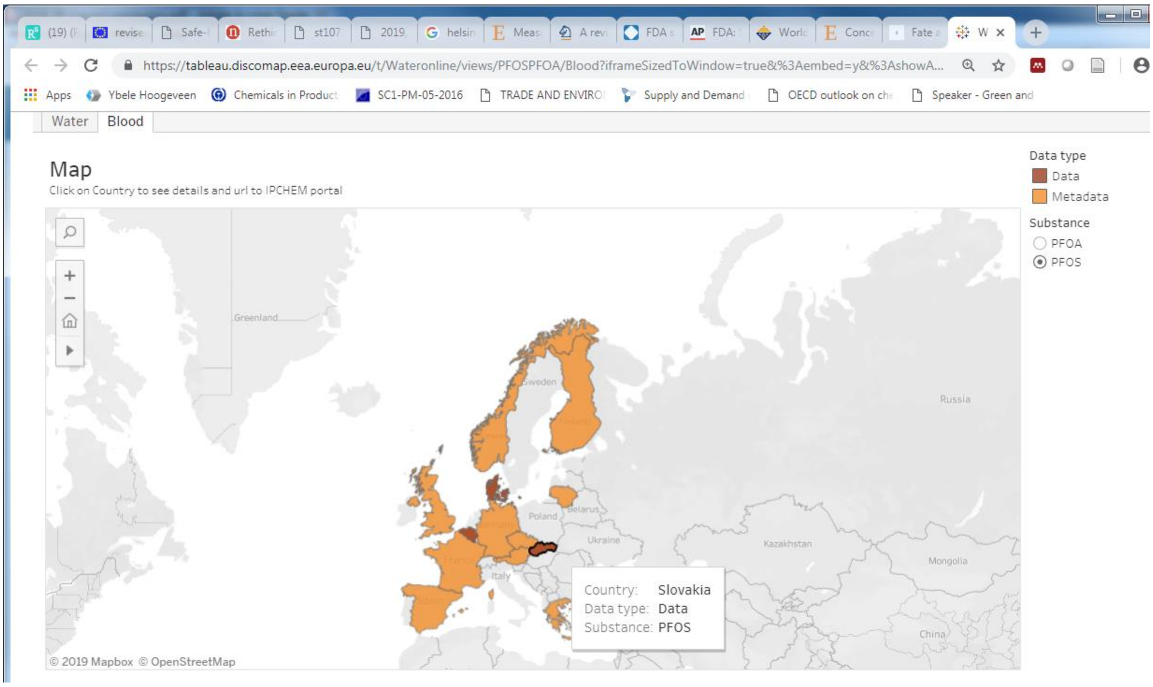


Evidence of PFAS pollution in humans exist from several national human biomonitoring studies both inside and outside of Europe, and is being investigated under EU research initiatives such as the HBM4EU project (Box 2). The maps 3 and 4 show the levels of PFOA and PFOS in blood of infants, teenagers and adults in Belgium, Slovakia and Denmark. This data is drawn from studies that took place over the period 2005 to 2014.

Map 3 – PFOA in the blood of infants, teenagers and adults in Belgium, Slovakia and Denmark, sampled over the period 2005-2014



Map 4 - PFOS in the blood of infants, teenagers and adults in Belgium, Slovakia and Denmark, sampled over the period 2005-2014



Sources:

- Odense Child Cohort
- Prospective cohort study of developmental origins of adult diseases in the Slovak population)
- Slovakian PCBcohort (PCBs AND EARLY CHILDHOOD DEVELOPMENT IN SLOVAKIA)
- FLemish Environment and Health Study 2 Hotspot Menen
- FLemish Environment and Health Study 2 Reference Adults
- FLemish Environment and Health Study 3 Reference Adults
- FLemish Environment and Health Study 3 Reference Newborns

Of the people sampled in these studies, 99.9-100 % had PFOA and PFOS in their blood, including new-born children. Levels increase with age, due to bioaccumulation. The median concentrations for PFOA were 0.9-1.3 ng/mL for in infants, and 1.7-3.5 ng/mL for adults. For PFOS, the median concentrations were 0.4-1.2 ng/mL in infants and 5.7-13 ng/mL in adults. The lowest levels for PFOS were seen in Slovakian cord blood, while the highest where detected in Belgium in the blood of adults near a polluted site. In Belgium, PFOS levels decreased from 13 ng/mL (in the period 2005-2010) to 7.6 ng/mL in 2014. Human biomonitoring studies in Europe and the US show consistent declines for the most regulated PFAS, such as PFOA and PFOS, but downward trends are less pronounced in the environment (Land 2018). The decrease in humans is therefore likely a result of actions taken to reduce exposure from consumer products, such as food contact materials. Meanwhile some longer chain PFAS and novel PFAS levels are either constant or increasing.

The PFOA and PFOS blood levels can be compared with the most recent EFSA bench mark dose levels known as $BMDL_5$, which reflects the concentration in human blood at which critical effects occur. They are based on cholesterol effects for adults and immune-toxicity for children (EFSA 2018), but do not take PFAS mixture toxicity into account. The $BMDL_5$ is the basis the provisional TWIs for PFOA and PFOS set by EFSA (EFSA, 2018), and is still discussed in EFSA and by science. The median concentrations detected in the Belgian, Danish and Slovakian studies correspond to 9-38 % of the $BMDL_5$ for PFOA and 4-55 % of the $BMDL_5$ for PFOS, implying that the $BMDL_5$ are not exceeded for the general population for the single PFAS. However, for the most highly exposed people in the studies (i.e. P95) levels are 26-68% of the $BMDL_5$ for PFOA and 11-140 % of the $BMDL_5$ for PFOS. These exceedances of the $BMDL_5$ for PFOS were seen in Belgium prior to 2014, and have since decreased to 84 % of the $BMDL_5$.

Workers such as firefighters, ski-waxers, and workers in fluorochemical plants typically have significantly elevated concentrations (EFSA 2018). A decrease in the levels of PFOS and PFOA in humans has been observed globally, and is likely a result of regulatory action to decrease the uses of PFAS (Land 2018). The slower observed decrease in levels of PFOA is likely due to the fact that unregulated polyfluorinated PFAS degrade to PFOA.

Box 2: HBM4EU is a 5-year research programme funded under the European Commission's Horizon 2020 programme, involving 29 partner countries and the European Environment Agency. The project aims to translate human biomonitoring science into policy-relevant knowledge. A main task within the project is to generate representative data on human exposure to HBM4EU priority substances in Europe. PFAS is one of the groups of substances under investigation. Activities include the development of limit values for PFAS in blood; understanding mixture effects; producing indicators of exposure to PFAS (e.g. Buekers 2018); and biomonitoring activities to generate new data on human exposure to PFAS.

How can consumers avoid PFAS?

It is difficult for citizens to totally avoid exposure to PFAS. Using PFAS-free personal care products and food contact materials, and avoiding direct contact with PFAS-containing products will clearly help reduce exposure. Using products from green labels, such as the EU Ecolabel and the Nordic Swan, can help to decrease exposure to PFAS. An increasing number of brands and retailers also sell a range of products that do not contain PFAS ingredients.

What is being done in the EU and globally?

A number of measures to reduce PFAS pollution are in place, which mainly address some well-known perfluorinated PFAS acids and their precursors. In Europe, countries such as Sweden, Denmark, Norway, Germany, Belgium, the Netherlands, Austria, Italy and France have been active in monitoring PFAS in environmental media as well as in humans and products, as well as in undertaking risk assessments, research and assessing alternatives to PFAS. Some of these countries have also set national limit values, supported by monitoring to enforce those values, e.g. for water and soil (Germany, the Netherlands, Sweden and Denmark), for textiles (Norway) and for food contact materials (Denmark).

Internationally, PFOS and PFOA are listed under Annex A of the Stockholm Convention, implying that parties to the Convention should take action to "eliminate the production and use" of the chemicals. At EU level, the Stockholm convention POPs are transposed into EU law, meaning that PFOS and PFOA are restricted under REACH. In addition, REACH restricts PFOA and its precursors in products, and a group of C6 fluorinated silanetriol derivatives, which means that limits also apply to imported products. A number of other PFAS are on the REACH list of Substance of Very High Concern (SVHCs), and in June 2019 GenX (HFPO-DA, a short-chain replacement for PFOA) was the first chemical added to the SVHC list on the basis of its persistent, mobile and toxic properties, posing a threat to drinking water and the environment. Meanwhile, several other long and short chain PFAS and their precursors are under scrutiny. Any substance listed as SVHCs or being restricted, is to be progressively replaced by less hazardous substances under the REACH Regulation. The European Chemicals Agency's (ECHAs) Community rolling action plan (CoRAP) lists substances that a Member State has or will evaluate over the coming years. EU Member States also report information on PFOA and PFOS in surface water under the Water Framework Directive. Outside of Europe, particularly in the US and Australia, public wide concern on PFAS has evolved in the past few years, upon the discovery of widespread environmental and human PFAS pollution around production, airbase, military and farmland sites, affecting millions of US citizens drinking water and leading to several large law-suits.

Looking ahead

With more than 4 700 known PFAS, it is not feasible to undertake highly scientific substance-by-substance risk assessments and comprehensive environmental monitoring.

As a result, additional precautionary measures are increasingly being called for by a number of European stakeholders in the 2014 Helsingør statement, the 2015 Madrid statement and in the Zürich Statement 2018. A key discussion is the whether to regulate PFAS subgroups (e.g. based on toxicity or chemical similarities) or a more precautionary approach to group PFAS as a class. Regulations supported by cost-effective monitoring of the class of PFAS could enable the early warning discovery of PFAS pollution, but need careful consideration of test methods that are fit for purpose (McDonough 2019), and how non-compliant results can trigger further action. The need for special attention on mixture effects and combined exposures, was underlined in the European Council of Ministers June 29th 2019 conclusions, and EFSA is currently considering how to address mixture toxicity of PFAS. Options to establish a new EU group limit value (0.5 µg/L), in addition to limits for 16 individual PFAS (0.1 µg/L) PFAS in drinking water, are currently being discussed between the European institutions.

The European Council of Ministers June 29th 2019 conclusions further highlighted the concern for the widespread occurrence of PFAS in the environment, products and in people, and called for an action plan to eliminate all non-essential uses of PFAS (Cousins 2019).

In terms of knowledge gaps, there is a critical need for the systematic mapping of sites suspected to be polluted with PFAS and local drinking water supplies to provide an early warning of potential human exposure. Techniques for the safe disposal of PFAS containing products also in need. Ensuring that product life cycles are made safer from the start (Warner 2016), e.g. based on the concept of safe-and-circular-by-design (van der Waals 2019) will be increasingly important, not only to protect the health Europe’s citizens, environment, and future generations, but also to maintain Europe’s leading position as a market that stimulates innovation in safer chemicals in support of Europe’s economy.