



Council of the
European Union

Brussels, 16 October 2020
(OR. en)

11976/20
ADD 5

ENV 634
CHIMIE 52
COMPET 507
IND 181
PHARM 44
AGRI 361
RECH 405
ECOFIN 945
ECO 46
SOC 624
SAN 364
CONSOM 175
MI 411
ENT 122

COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 16 October 2020

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

No. Cion doc.: SWD(2020) 249 final

Subject: COMMISSION STAFF WORKING DOCUMENT Poly- and perfluoroalkyl substances (PFAS) Accompanying the document COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Chemicals Strategy for Sustainability Towards a Toxic-Free Environment

Delegations will find attached document SWD(2020) 249 final.

Encl.: SWD(2020) 249 final



Brussels, 14.10.2020
SWD(2020) 249 final

COMMISSION STAFF WORKING DOCUMENT

Poly- and perfluoroalkyl substances (PFAS)

Accompanying the document

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE AND THE COMMITTEE OF THE REGIONS**

**Chemicals Strategy for Sustainability
Towards a Toxic-Free Environment**

{COM(2020) 667 final} - {SWD(2020) 225 final} - {SWD(2020) 247 final} -
{SWD(2020) 248 final} - {SWD(2020) 250 final} - {SWD(2020) 251 final}

COMMISSION STAFF WORKING DOCUMENT

Poly- and perfluoroalkyl substances (PFAS)

1. What are PFAS: properties, uses, concerns and sources of emissions

Poly- and perfluoroalkyl substances (PFAS) are a group of widely used man-made organic chemical substances.

They contain alkyl groups¹ on which all or many of the hydrogen atoms have been replaced with fluorine². Well known PFAS contain fully fluorinated carbon chains³ of various chain lengths attached to a functional group, like carboxylic or sulfonic acids. Such groups are called perfluorinated acids and include PFOA⁴ and PFOS⁵. Shorter chain PFAS have been developed more recently to substitute the longer chain ones. In this context, an important distinction is the one between “long chain” and “short chain” PFAS⁶.

The PFAS group includes also polymers: e.g. fluoropolymers⁷, perfluoropolyethers⁸ and side-chain fluorinated polymers⁹.

The OECD has published a clear explanation of the different groups of PFAS¹⁰. Examples of typical PFAS structures are shown in Figure 1.

¹ An alkyl is a functional group that contains only carbon and hydrogen atoms.

² In Buck et al. (2011) the definition of per- and polyfluoroalkyl substances (PFAS) was “the highly fluorinated aliphatic substances that contain 1 or more C atoms on which all the H substituents have been replaced by F atoms, in such a manner that they contain the perfluoroalkyl moiety $C_nF_{2n+1}-$ ” (where n is equal to or greater than 1, i.e. the structure must contain at least one CF_3- group). In 2018, OECD Global PFC Group defined PFAS as chemicals with at least one perfluorocarbon moiety ($-C_nF_{2n}-$).

³ In a fully fluorinated carbon chain, all hydrogen atoms have been replaced by fluorine.

⁴ PFOA is the abbreviation for Perfluorooctanoic acid

⁵ PFOS is the abbreviation for Perfluorooctane sulfonic acid

⁶ “Long-chain PFAS” include perfluoroalkyl carboxylic acids (PFCA) with 7 or more perfluorinated carbons, perfluoroalkane sulfonic acids (PFSA) with 6 or more perfluorinated carbons, and their precursors. This distinction applies only to PFCAs, PFSA and their precursors.

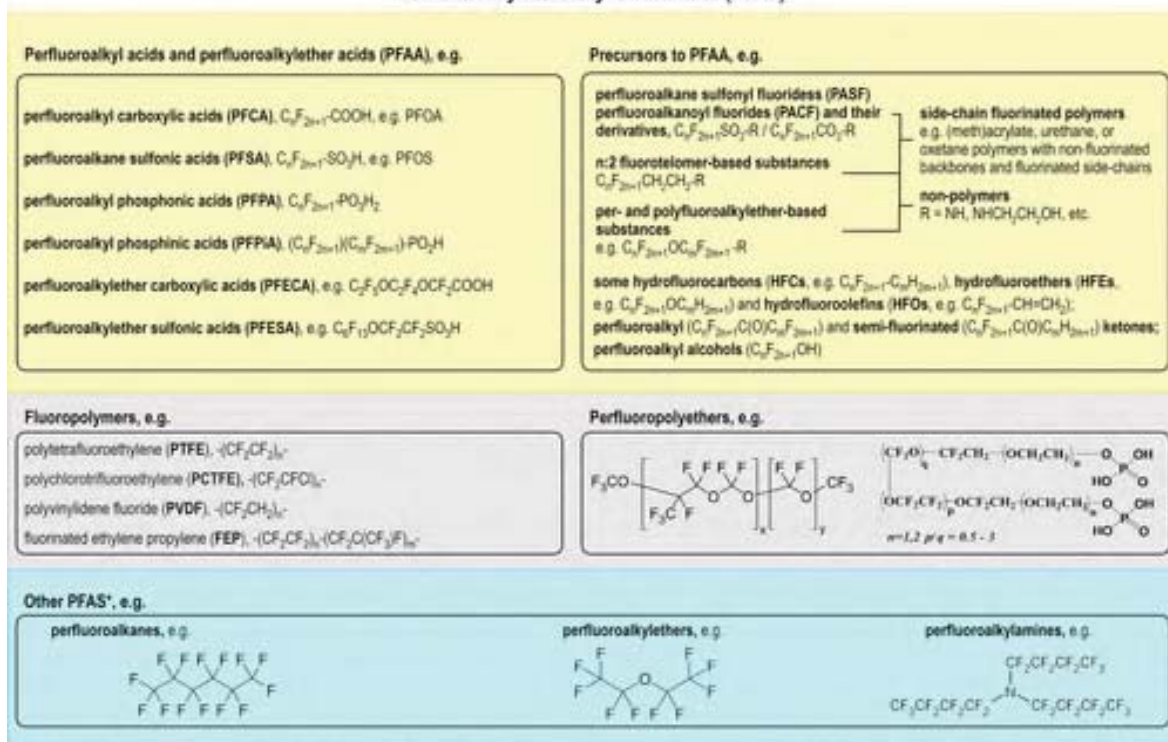
⁷ Fluoropolymers have a carbon-only backbone with fluorine atoms directly attached to it.

⁸ Perfluoropolyethers have a carbon and oxygen backbone with fluorine atoms directly attached to the carbon atoms.

⁹ Side-chain fluorinated polymers have a non-fluorinated backbone with fluorinated side chains.

¹⁰ <https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/aboutpfass/Figure1-classification-of-per-and-polyfluoroalkyl-substances%20-PFASs.pdf>

Per- and Polyfluoroalkyl Substances (PFAS)



* These PFAS have been less discussed in the public domain, but they meet the definition of PFAS as recommended in Buck et al. (2011) and OECD (2018). They are primarily PFAS with limited chemical reactivity.

Figure 1: Examples of PFAS chemistries. From Kwiatkowski et al. (2020), Environ. Sci. Technol. Lett. 2020, 7, 8, 532-543

Functional groups in PFAS substances can be variable¹¹, and this variability explains both the large number of PFAS and their different applications. A 2015 study reported that more than 3,000 PFAS were on the global market for commercial use¹². In 2018, the OECD found over 4,700 different CAS numbers for PFAS¹³. The number of PFAS commercially produced and used could be even higher, as in some cases their identities are considered confidential business information and impurities and by-products are not declared.

The carbon-fluorine bond is extremely strong and stable¹⁴. When the non-polar fluorocarbon chain is linked to a polar structure, the PFAS become surfactants. These characteristics give PFAS very useful properties, such as oil and water repellence, high chemical, physical and temperature resistance and ability to act as surfactants. Because of such properties and of the structural variability due to the functional groups, PFAS have been used in a wide variety of products and industrial applications. Their uses include polymerisation aids in fluoropolymers production, surfactants in fire-fighting foams, anti-mist agents in chromium plating, water-

¹¹ Examples of functional groups include alcohols (-OH), amines (-NH₂), halogens (-F, -Cl, -Br, -I), esters (-CO₂R), ethers (-O-), thiols (-SH), carboxylic acids (-CO₂H), sulfonic acids (-SO₃H), sulfonic acids (-SO₂H), sulfones (-SO₂R), phosphate acids (-PO(OH)₂), phosphinic acids (-PO(OH)), as well as their derivatives, including salt forms and polymers (OECD 2018, Glüge et al. 2020).

¹² Swedish Chemicals Agency (2015), *Occurrence and use of highly fluorinated substances and alternatives: Report from a government assignment*.

¹³ For a list of 4,730 PFAS-related CAS numbers compiled from publicly accessible sources of information, see OECD (2018), *Toward a new comprehensive global database of per and polyfluoroalkyl substances (PFASs): summary report on updating the OECD 2007 list of per and polyfluoroalkyl substances (PFASs)*.

¹⁴ https://en.wikipedia.org/wiki/Carbon%E2%80%93fluorine_bond

and oil repellence in textiles, leather, food contact materials and cosmetics. They are also used in the production of components of semiconductors and medical devices, as co-formulant in plant protection products, biocides, feed additives, pharmaceuticals and paints. A recent study identified more than 200 use categories and subcategories for more than 1400 individual PFAS¹⁵.

The very strong bond between carbon and fluorine, that gives PFAS their properties, is also responsible for their main concern: they are persistent. While some of the more complex molecules can partially degrade, they will ultimately form a PFAS that is persistent in the environment (such as PFOA or PFOS and smaller perfluorinated substances). Substances with a non-fluorinated (hydrocarbon) part in addition to their PFAS-elements often degrade until they reach persistent PFAS degradation products¹⁶.

Another characteristic shared by some of the short-chain and generally small PFAS is their mobility in the environment¹⁷. This property, combined with persistency, causes PFAS accumulation in water bodies, drinking water, plants and air. A large number of PFAS contamination cases of water (including drinking water¹⁸) and soil have been detected in the EU and globally¹⁹. Some PFAS can be highly mobile in air, leading to their accumulation and transport over long distances²⁰.

Several PFAS can also bioaccumulate²¹ in humans, animals and plants and, among the few that are well studied, most are considered to be toxic. Some PFAS are classified as Persistent, Bioaccumulative and Toxic (PBT) and very Persistent and very Bioaccumulative (vPvB) under REACH²². The European Environment Agency²³ lists the main effects of PFAS on human health, which include thyroid disease, increased cholesterol levels, effects on reproduction and fertility, immunotoxicity, liver damage, kidney and testicular cancer. Immunotoxicity and endocrine effects have been reported for some PFAS. A recent opinion from the European Food Safety Agency (EFSA) concluded that both PFOS and PFOA are associated with reduced antibody response to vaccination. PFOS also causes a reduced resistance to infection. EFSA concluded that parts of the European population exceeds the tolerable weekly intake from food of four PFAS²⁴. Reported effects of PFAS on aquatic and terrestrial animals include survival, growth, development and reproduction²⁵.

A main source of PFAS to humans and the environment is their production and use in industrial and professional installations, e.g. as production of fluoropolymers, use of fire-

¹⁵ Gluge et al (2020), *An overview of the uses of per- and polyfluoroalkyl substances (PFAS)*. Accepted for publication.

¹⁶ Liu et al. (2014), *Microbial degradation of polyfluoroalkyl chemicals in the environment: a review*. Butt et al. (2013), *Biotransformation pathways of fluorotelomer-based polyfluoroalkyl substances: a review*.

¹⁷ Kwiatkowski et al. (2020), *Scientific basis to manage PFAS as a chemical class*

¹⁸ WHO (2017), *Keeping our water clean: the case of water contamination in the Veneto Region, Italy*.

¹⁹ Nordic Council of Ministers (2019), *The cost of inaction*, chapter 4 « The case studies »

²⁰ Young et al (2010), *Atmospheric perfluorinated acid precursors: chemistry, occurrence, and impacts*

²¹ Ian T. Cousins (2017), *Per- and polyfluoroalkyl substances in materials, humans and the environment*.

²² Perfluorohexane sulphonic acid (PFHxS) and its salts, perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA) and its salts, nonadecafluorodecanoic acid (PFDA) and its salts (<https://echa.europa.eu/candidate-list-table>)

²³ <https://www.eea.europa.eu/themes/human/chemicals/emerging-chemical-risks-in-europe>

²⁴ <https://www.efsa.europa.eu/en/news/pfas-food-efsa-assesses-risks-and-sets-tolerable-intake>. EFSA assessed the combined exposure from four PFAS: PFOA, PFNA, PFHxS and PFOS.

²⁵ https://www.mfe.govt.nz/sites/default/files/media/Land/final-impact-of-pfas-on-ecosystems_0.pdf

fighting foams, use in the production of textiles, paints and printing inks and food contact materials. Another source is the release from consumer products, such as textiles, polishing and cleaning products, cosmetics and food contact materials, during their use and at the end of their life. PFAS can be released to the environment from industrial and municipal waste-water treatment plants, landfills, recycling and incineration plants and from re-use of contaminated sewage sludge. The number of sites potentially emitting PFAS has been estimated to be approximately 100 000 in Europe²⁶.

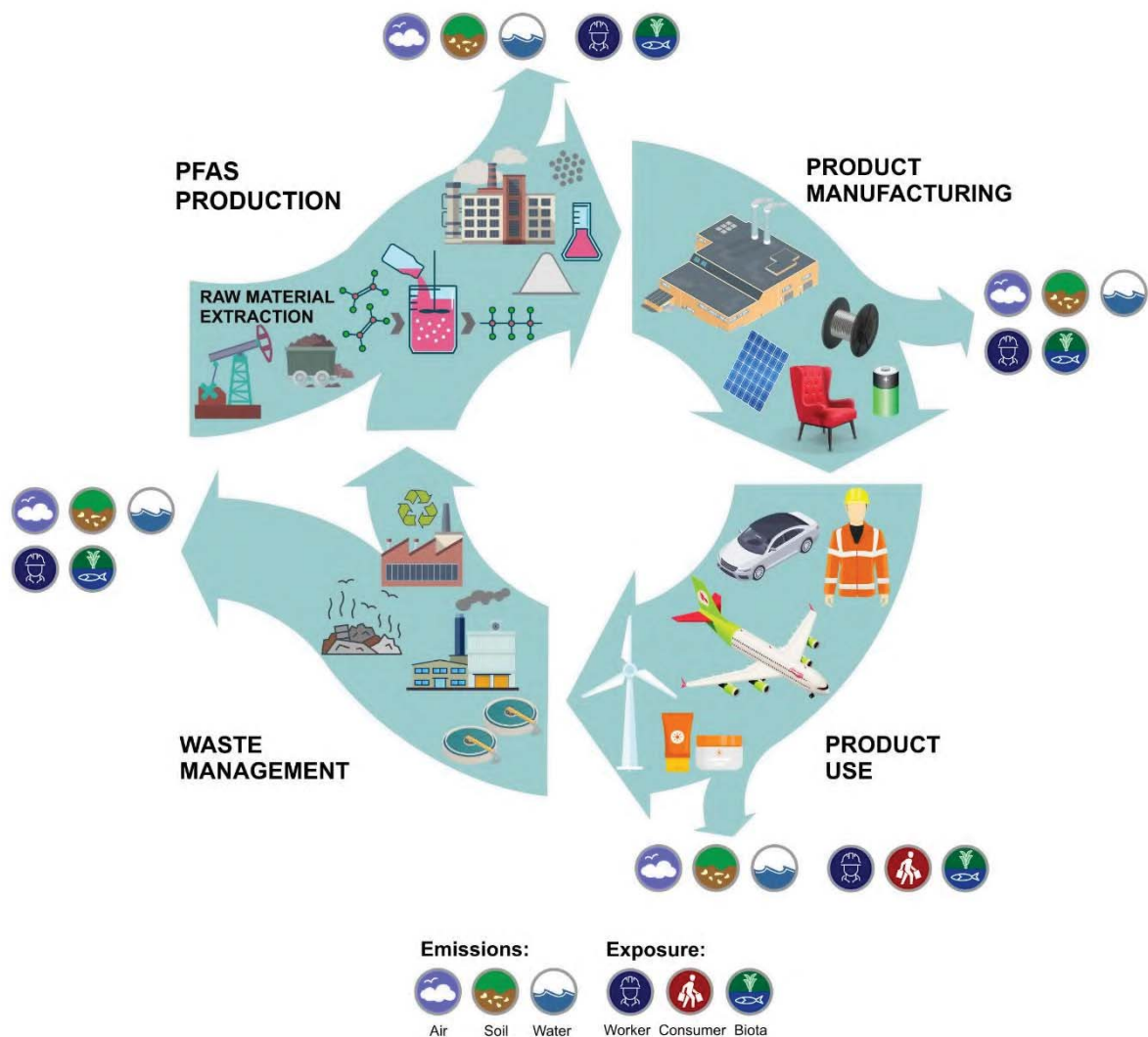


Figure 2: emission of and exposure to PFAS during their lifecycle (source: EEA-ETC report, Systemic view on fluorinated polymers, forthcoming 2020).

2. Existing regulations on PFAS, in the EU and globally

Some PFAS have been regulated in Europe and internationally. This is the case for PFOA, PFOS and chemicals that can degrade to them (part of the group of “long chain PFAS”), which were widely used in the past mostly as polymerisation aids, in fire-fighting foams, in

²⁶ The Nordic Council of Ministers (2019), *The Costs of Inaction. A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS*

textile treatment, in medical devices and semiconductors. They are PBTs or vPvBs and they are found in the environment, in humans and in animals, sometimes far from contamination sources. For these reasons, PFOA and PFOS have been listed under the Stockholm Convention on Persistent Organic Pollutants (POPs) and as a consequence, are now restricted under the EU POPs Regulation²⁷.

Another long-chain PFAS (PFHxS)²⁸, less widely used than PFOA and PFOS but often found in the environment and in human biomonitoring, is currently being assessed for a restriction under REACH²⁹ and is also considered for listing under the Stockholm Convention³⁰.

Some longer chain PFAS (C9-C14 PFCAs) are not known to be intentionally used in the EU, but they can be present as impurities during the manufacture of other PFAS. A restriction process under REACH is ongoing for those substances³¹.

When the regulatory processes on long-chain PFAS started, industry developed other fluorinated substances (the so called “short chain PFAS”) as alternatives.

Although some of the short-chain PFAS alternatives are less bioaccumulative, they are equally persistent in the environment as the substances they replace³². This means that they could still lead to adverse effects, if people are continuously exposed, and to accumulation in the environment. Moreover, there is evidence of higher uptake in vegetables than the long-chain PFAS³³, which indicates a potential to contaminate food sources.

Because of these concerns, some of the short-chain PFAS are starting to be regulated under the EU chemicals legislation (REACH³⁴).

HFPO-DA (better known as Gen-X) has replaced PFOA as processing aid for producing fluoropolymers. In 2019, it was identified as a Substance of Very High Concern (SVHC)³⁵ on the basis of its high potential to cause effects in wildlife and in humans due to its very high persistence, mobility in water, potential for long-range transport, accumulation in plants and observed effects on human health and the environment. At the time of identification, the responsible body (the Member State Committee of the European Chemicals Agency, ECHA) also indicated as a concern the potential exposure through the food chain and drinking water, as well as difficulties to remediate polluted media and remove HFPO-DA from drinking water.

²⁷ Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on Persistent Organic Pollutants. PFOA has been listed in Annex I of the POPs Regulation with Regulation (EU) 2020/784.

²⁸ <https://echa.europa.eu/substance-information/-/substanceinfo/100.259.368>

²⁹ <https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1827f87da>

³⁰ <http://chm.pops.int/Convention/POPsReviewCommittee/Chemicals/tabid/243/Default.aspx>

³¹ <https://echa.europa.eu/substance-information/-/substanceinfo/100.256.331>

³² Schering M et al. (2014), *Helsingør Statement on poly- and perfluorinated alkyl substances (PFASs)*

³³ Krippner et al. (2014), *Effects of chain length and pH on the uptake and distribution of perfluoroalkyl substances in maize (Zea mays)*. Blaine et al. (2014), *Perfluoroalkyl acid uptake in lettuce (Lactuca sativa) and strawberry (Fragaria ananassa) irrigated with reclaimed water*.

³⁴ <https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas>

³⁵ <https://echa.europa.eu/registry-of-svhc-intentions/-/dislist/details/0b0236e1832708a2>

Perfluorobutane sulfonic acid (PFBS) is also used in the production of fluoropolymers. In 2020, it was identified as a SVHC³⁶ on the basis of its very high persistence, high mobility in water and soil, high potential for long-range transport, and difficulty of remediation and water purification as well as moderate bioaccumulation in humans. Other concerns included probable serious effects for human health and the environment.

Germany has proposed PFHxA and its precursors for a restriction under REACH³⁷. These are also short-chain PFAS developed as alternatives to the restricted long-chain ones for use in fire-fighting foams, in the production of fluoropolymers and in treatment of textiles. The ECHA Scientific Committees are currently assessing the restriction dossier.

A group of Member States and Norway have recently announced the intention to work on a restriction under REACH covering all uses of the whole group of PFAS³⁸.

Apart from the chemicals legislation, some PFAS are regulated, or in the process of being regulated, under the water and food legislations. The details are presented in chapters 6 and 8 respectively.

3. Why the existing regulatory actions are not sufficient to address PFAS concerns

The ban of widely used long-chain PFAS has led to their substitution with a large number of shorter chain PFAS. Several of these alternatives are now under regulatory scrutiny in the REACH Regulation because of the concern they pose for the environment and for human health. There is little information on production volumes, uses, properties, toxicological profiles and biological effects of many of these substances. Because of the high number of different PFAS that can be produced for the same uses, each PFAS can be individually produced at a rather low tonnage. Moreover, many PFAS are polymers, currently not subject to registration under REACH. The low production volumes and polymer status limit the information available on many PFAS.

In some cases, the short-chain PFAS have a lower performance than the long-chain PFAS, requiring larger quantities for a specific use, leading to higher emissions³⁹. This is for example the case of uses in the treatment of textiles. Thus, it is likely that the widespread and increasing use of short-chain PFAS will lead to environmental and human exposure, to an increasing environmental concentration and possibly to adverse effects, repeating the problem caused by the long-chain PFAS.

The concerns are not limited to short-chain PFAS. While most of the commercial uses of long-chain PFAS are restricted or in the process of being restricted in the EU, they continue to be produced as by-products during the manufacturing process of the short-chain alternatives

³⁶ <https://echa.europa.eu/registry-of-svhc-intentions/-/dislist/details/0b0236e182bbccf8>

³⁷ <https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18323a25d>

³⁸ <https://www.rivm.nl/qas-pfas-restriction-proposal>, <https://www.reach-clp-biozid-helpdesk.de/SharedDocs/Meldungen/DE/REACH/2020-05-08-RMOA-PFAS.html>

³⁹ Scheringer M et al. (2014), [Helsingør Statement on poly- and perfluorinated alkyl substances \(PFASs\)](#)

and, as a consequence, they can be emitted. They are also present as impurities in the alternatives. Because some of them can be transported over long distances, emissions from production and use outside the EU will lead to exposure in the EU. Their presence in articles produced before the entry into application of the restrictions is going to represent a continuous source of emissions to the environment also in the future.

A fundamental problem of the approach followed until now for PFAS is that it is limited to individual substances or groups of closely related substances. The high number of substances and the lack of information on each specific substance makes it impossible to assess all PFAS substance-by-substance.

The long-term socioeconomic costs of the PFAS emitted to the environment are difficult to assess. Because of their high persistence, PFAS released over the whole lifecycle of a product will remain in the environment for an indefinite time. One of the main concerns is that the contamination in some cases may be irreversible, making fundamental natural resources such as soil and water no longer usable.

The Nordic Council⁴⁰ has looked at how the production and use of PFAS, including end-of-life disposal, have resulted in widespread environmental contamination and human exposure. It has presented several case studies of contamination in Europe, from PFAS manufacturing facilities, manufacture of PFAS-containing products, use of fire-fighting foams and of consumer products e.g., cosmetics, textiles and food contact materials. This study has estimated the costs for society related to PFAS, including health related costs and costs for remediation of contaminated water and soil. Findings indicate that the costs are substantial, with annual health-related costs estimated to 52 – 84 billion EUR for all EEA countries. While, on the one hand, uncertainties in the analysis need to be acknowledged, on the other hand, the findings could be considered conservative and may increase over time in case the production volume of PFAS keeps increasing.

A group of leading scientists studying PFAS has published statements, i.e., the Helsingør Statement⁴¹, the Madrid Statement⁴², and the Zurich Statement⁴³ highlighting the health and environmental risks posed by PFAS and the need to regulate them as a group, as well as asking for their production and use to be limited. The proposal to group all PFAS for regulatory action is based on concerns related to the high persistence of PFAS, the lack of knowledge on chemical structures, properties, uses, and toxicological profiles of most PFAS currently in use.

⁴⁰ The Nordic Council of Ministers (2019), [*The Costs of Inaction. A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS*](#)

⁴¹ Scheringer M et al. (2014), [*Helsingør Statement on poly- and perfluorinated alkyl substances \(PFASs\)*](#)

⁴² Blum A et al. (2015), [*The Madrid Statement on Poly- and Perfluoroalkyl Substances \(PFASs\)*](#)

⁴³ Ritscher A et al. (2018), [*Zürich Statement on Future Actions on Per- and Polyfluoroalkyl Substances \(PFASs\)*](#)

Industries producing PFAS have replied to the Madrid statement, underlining the different environmental and human health impacts due to the structural variability of PFAS and the societal benefits of their use⁴⁴.

In June 2019, the Council of the European Union noted “the growing evidence for adverse effects caused by exposure to highly fluorinated compounds (PFAS), the evidence for widespread occurrence of PFAS in water, soil, articles and waste and the threat this may cause to our drinking water supplies” and asked the Commission to “develop an action plan to eliminate all non-essential uses of PFAS”⁴⁵.

In December 2019, some Member States and Norway sent a letter to the Commission to ask for an EU action plan to address the concern posed by PFAS and provided some suggestions on its possible content⁴⁶.

In July 2020, the European Parliament adopted a resolution on the Chemicals Strategy for Sustainability⁴⁷ asking the Commission to “ensure the speedy phasing out of all non-essential uses of PFAS, and to accelerate the development of safe and non-persistent alternatives to all uses of PFAS”.

4. A possible way forward to address PFAS concern

The regrettable substitution seen in the case of long-chain PFAS and the very high number of PFAS on the market show that the approach taken until now of regulating them individually (or in small groups of closely related substances) is not efficient and does not fully address the concerns they pose. This leads to the conclusion that it would be beneficial if, as far as possible, future regulatory initiative concerning PFAS address them as a **group**.

Recent publications have investigated various approaches that could be taken to regulate PFAS as a chemical class⁴⁸ or as sub-groups, based on their intrinsic properties (e.g. persistence, bioaccumulation potential, toxicity, mobility, molecular size)⁴⁹. The authors conclude that an approach to grouping based on persistence alone could be justified considering that the continuous release of persistent chemicals will lead to widespread, long-lasting, irreversible and increasing contamination. It will also result in increasing probabilities of adverse effects on human health and the environment, especially for substances that, as PFAS, can contaminate soil, water and the food chain.

⁴⁴ Bowman (2015), *Fluorotechnology is critical to modern life: the FluoroCouncil counterpoint to the Madrid Statement*.

Social benefits of PFAS include producing durable and lightweight tubing in aircrafts, trucks, and buses, enabling high-speed data transfer for wireless communications, or providing protective surface finishes for textiles such as surgical gowns that shield against pathogens.

⁴⁵ <http://data.consilium.europa.eu/doc/document/ST-10713-2019-INIT/en/pdf>

⁴⁶ <https://www.regjeringen.no/contentassets/1439a5cc9e82467385ea9f090f3c7bd7/fluor---eu-strategy-for-pfass---december-19.pdf>

⁴⁷ https://www.europarl.europa.eu/doceo/document/TA-9-2020-0201_EN.html

⁴⁸ Kwiatkowski et al. (2020), *Scientific basis to manage PFAS as a chemical class*

⁴⁹ Cousins et al, (2020) “Strategies for grouping per- and polyfluoroalkyl substances (PFAS) to protect human and environmental health”

If more and more legislations start to address PFAS as a group, there will be a need for **analytical methods** to measure all PFAS. There are methods available to measure individual PFASs (mostly those already regulated) with a sufficient specificity and sensitivity. Some methods have been developed to measure organic fluorine content as surrogate for PFAS⁵⁰, but they may include also fluorine from other sources. Another method measures the presence of PFAS precursors⁵¹, but it does not detect all PFAS. Both methods are semi-quantitative. Such non-specific methods could be useful screening tools to detect and quantify the presence of more PFAS in different matrices. While methods with adequate performances exist for e.g. water, sludge and biota, their applicability and sensitivity will need to be adapted to the specific legal purposes.

The very large number of uses of PFAS, including some critical for society (for example, medical devices), show that some of their uses can bring high socio-economic benefits. Such benefits should be compared with the socio-economic costs of the environmental contamination and of the adverse effects on human health. A concept that could be useful in this assessment, with the purpose of reducing emissions, is that of “**essential uses**”.

It was first applied in the Montreal Protocol⁵², which defines a use as essential if it is “necessary for health, safety or is critical for functioning of society” and “there are no available technically and economically feasible alternatives”. A recent paper⁵³ has tried to apply this approach to PFAS, attributing some of their uses to different essential categories. The authors argue that many uses of PFAS can be phased-out because they are not necessary for the betterment of society or because there are non-fluorinated alternatives available. Only the uses of PFAS that are critical for society and which currently do not have alternatives that provide the same level of performance should be allowed. For such uses, society could accept the related costs, until suitable alternatives are available.

An example could be the use of PFAS to provide water and oil repellence to textiles. While alternatives that provide water repellence are available, they do not yet have the same performance as PFAS for oil repellence. For certain consumer uses, oil repellence could be considered convenient but not essential, and alternatives could therefore replace PFAS. On the other hand, for some workers protection clothes oil repellence could be essential to ensure a high level of protection, then PFAS should be allowed to be used until suitable alternatives are available.

Because of the many sources of PFAS in the environment and considering their high persistence, in addition to limiting the emissions at the source, there is a need to identify and reduce existing pollution in the different environmental compartments. Restricting PFAS uses under the chemical and products specific legislations could therefore be complemented with actions under other legislative frameworks (water, food, industrial emissions, waste) and non-legislative initiatives (soil).

⁵⁰ An overview of these methods was recently published by Koch et al. (2020), “Towards a comprehensive analytical workflow for the chemical characterisation of organofluorine in consumer products and environmental samples”.

⁵¹ The TOP assay (TOPA) is a method to reveal the presence of any PFCA and PFSA precursors by oxidative conversion

⁵² United Nations, Montreal Protocol, on substances that deplete the ozone layer, 1987, Decision IV/25

⁵³ Cousins et al. (2019), *The concept of essential use to determine when uses of PFAS can be phased out*

The next chapters will look at the regulatory and non-regulatory approaches that could be used to address PFAS concerns in the EU and globally, by presenting the contribution that each initiative could provide, in addition to the actions already taken or that are on-going. Most of the regulatory initiatives presented include public consultations, which would allow stakeholders to be informed and provide input on the planned regulatory actions.

The regulatory and non-regulatory actions identified need to be supported with research and innovation activities, to identify alternative substances and technologies and to address existing contamination cases. This is discussed in detail in chapter 13.

5. Chemicals legislation

5.1 A REACH restriction on all PFAS

The chemicals legislation (REACH) has a very effective tool to manage the risk from substances, such as PFAS, that are used in industrial processes but also in products: the restriction. A restriction can ban the manufacture, placing on the market or use of a chemical substance, or a group of substances. It applies also to imported products and it is flexible, because it can include derogations, unlimited in time or time limited. A REACH restriction is an appropriate EU instrument to address PFAS concerns at the source.

The European Commission has initiated two studies regarding a possible REACH restriction covering all uses of PFAS in fire-fighting foams and textiles (including upholstery, apparels, carpets and leather). These are among the uses with the largest emissions to the environment. The study on fire-fighting foams has recently been published⁵⁴.

In parallel, as presented in chapter 2, a group of Member States and Norway have initiated preliminary work on a **REACH restriction covering all uses of all PFAS**. The restriction dossier could be ready in 2022, for a discussion in Scientific Committees of the European Chemicals Agency (ECHA) in 2022-2023 and a potential entry into force in 2025.

The use in fire-fighting foams is responsible for a large number of cases of contamination⁵⁵. Users such as in airports and industrial sites are currently in the process of replacing the fire-fighting foams containing long-chain PFAS because of the entry into application of the PFOA restriction in the POPs Regulation⁵⁶. As the Commission study shows, fluorine-free fire-fighting foams are available for most of the uses. There is an advantage to proceed with a restriction on all PFAS in fire-fighting foams before the restriction covering all the other uses as users would know that further regulation is coming for PFAS-based fire-fighting foams and would avoid the costs of a second regrettable substitution. Moreover, the substitution to

⁵⁴ https://echa.europa.eu/documents/10162/28801697/pfas_flourine-free_alternatives_fire_fighting_en.pdf/d5b24e2a-d027-0168-cdd8-f723c675fa98

⁵⁵ Nordic Council of Ministers (2019), *The cost of inaction*, Case study 4.3: Contamination from use of aqueous film-forming foams

⁵⁶ Regulation (EU) 2020/784

fluorine-free alternatives would happen earlier, reducing the risks of additional contaminations.

For these reasons, the European Commission has asked ECHA to develop an **Annex XV restriction dossier for the use of PFAS in fire-fighting foams**⁵⁷. This dossier could serve as a case-study for the broad restriction on PFAS, supporting the Member States' and Norway's work. For example, the discussions in ECHA's Risk Assessment Committee on the approaches to the hazard assessment of PFAS in the case of the fire-fighting foams will inform the dossiers submitters of the broad restriction for their own assessment.

The Commission's study on PFAS in textiles, upholstery, apparels, carpets and leather is intended to further support the work of the Member States and Norway.

As described in chapter 4, one way to address the concern of PFAS under the chemicals and products legislations could be to ensure that the use of PFAS is allowed only when essential for society. The authorities working on the broad restriction dossier intend to restrict all uses of PFAS except those that are essential⁵⁸. However, at present there is no agreed definition of what is an essential use or what criteria could be used to define those uses. The European Commission could contribute to the debate by developing a **policy document on the concept of essential uses**, to be discussed with the Competent Authorities for REACH, using PFAS as a case study.

As discussed in chapter 1, several **PFAS** are **polymers**, and as such, under REACH Art. 3(5), are currently not subject to REACH registration. A study on the development of criteria to identify and group polymers for registration under REACH was recently published⁵⁹. The study is intended to provide a basis for discussions between stakeholders, Member States and the European Commission on which polymers could be subject to the REACH registration requirement. The outcome of those discussions will feed into an impact assessment with the objective to develop a **proposal for REACH registration of polymers of concern**.

It is well known that PFAS polymers are persistent and can contain non-polymeric PFAS used in the production process (for example, as polymerisation aids) as impurities⁶⁰. While polymers can be covered by the PFAS restrictions, some essential uses for which there are currently no alternatives might be derogated. The REACH registration would allow access to information such as production volumes, presence of residual oligomers and monomers, other impurities and degradation products for polymers and uses derogated from the restriction.

As also mentioned in chapter 4, to ensure a proper implementation and enforcement of the restrictions, there will be a need for validated **analytical tests** to measure PFAS as a chemical class in different matrices, at sufficiently high sensitivity. Analytical tests are further discussed in chapter 6 on water legislations.

⁵⁷ <https://echa.europa.eu/current-activities-on-restrictions>

⁵⁸ <https://www.rivm.nl/qas-pfas-restriction-proposal>

⁵⁹ <https://op.europa.eu/s/ohY1>

⁶⁰ Lohman et al., (2020), "Are fluoropolymers really of low concern for human and environmental health and separate from other PFAS?" Environmental Science and Technology, Accepted for publication Oct 1, 2020

As explained in chapter 1, PFAS are used in applications that are covered by specific legislations, such as cosmetics, food contact materials, plant protection products and biocides. Such uses could all be covered by the restriction to achieve a high level of protection. Some sector-specific legislations are described below, outlining how they could complement the REACH restriction.

5.2 PFAS in sector-specific legislations

Food contact materials

PFAS are widely used in food contact materials for their oil and water repelling properties. Regulation (EC) 1935/2004 covers materials that come into contact with food. This Regulation sets out general rules and provides the basis for specific EU measures that cover certain materials, including plastic (Regulation (EU) 10/2011). The Regulation contains a list of substances permitted for use in plastic food contact materials, which includes several PFAS. While those PFAS have been authorised for use in plastics because their use in contact with food does not cause health concerns, the production of those food contact materials and their eventual disposal is subject to the same general environmental concerns that the use of PFAS raises. Regulation (EC) 1935/2004 however does not allow for sufficient flexibility to anticipate concerns other than the health risks related to the use in contact with food.

The Commission is presently **reviewing Regulation (EC) No 1935/2004** and it will be subject to an impact assessment. The interface with other legislation, and with REACH in particular, will be considered during that assessment to increase coherence and synergy.

Plant protection products

Annex III of Regulation (EC) 1107/2009 lists co-formulants not accepted for use in plant protection products. The REACH restriction in preparation aims to cover this use of PFAS and could be followed by the **listing of PFAS in Annex III to Regulation (EC) 1107/2009**.

6. Water legislations

Drinking water directive

Directive 98/83/EC was recently reviewed and, as a result, standards for PFAS in drinking water were introduced. The new Directive (to be adopted by the end of 2020) includes in Annex I a limit value of 0.1 µg/L for a sum of 20 individual PFAS listed in Annex III⁶¹, as well as a limit value of 0.5 µg/L for total PFAS concentration. The limit value of 0.5 µg/L will only apply once a method for measuring “PFAS total” is available. The Commission

⁶¹ PFBA, PFPA, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFUnDA, PFDoDA, PFTrDA, PFBS, PFPS, PFHxS, PFHpS, PFOS, PFNS, PFDS, perfluoroundecane sulfonic acid, perfluorododecane sulfonic acid, perfluorotridecane sulfonic acid.

organised a workshop in January 2020 to discuss possible analytical methods for the measurement of “PFAS total”⁶².

The new Directive requires the Commission, supported by ECHA, to establish within 4 years after entry into force of the Directive, an EU positive list of substances to be used in materials in contact with drinking water. This shall be based on positive lists available in the Member States.

To ensure that the **materials coming in contact with drinking water** are safe against possible PFAS contamination, the **EU positive list** could consider the REACH restrictions, the maximum levels for the assessed PFAS substances in food and other available risk assessment information.

Groundwater Directive

The 2014 review of the Groundwater Directive (2006/118/EEC) annexes led to an initiative, started in 2015, to obtain information on substances posing a potential risk (emerging pollutants) in groundwater to include them in a voluntary Ground Water Watch List (GWWL) and possibly in the annexes of the Directive. PFAS was one of the first groups assessed⁶³, for which 11 Member States provided monitoring data.

Where sufficient monitoring data is available from a relevant number of sites at EU level, the **amendment of Annex I and/or II of the Groundwater Directive** could be considered to include at least the 10 PFAS⁶⁴ already identified in the watch list process as posing a risk

Depending on availability of data and suitable analytical methods, **additional PFAS could be included in the watch list**, with the aim of eventually **covering all known PFAS in the Annexes**.

Water Framework Directive

The Water Framework Directive (WFD, Directive 2000/60/EC) Annex X lists chemicals that are of concern in surface waters. The Directive on Environmental Quality Standards (EQS)⁶⁵ sets the quality standards to be achieved for each substance in surface water bodies.

There are two classes of chemicals: priority substances (for which emissions need to be reduced progressively) and the subset of priority hazardous substances (for which emissions should also cease). PFOS (and its derivatives) is the only PFAS currently listed as a priority hazardous substance. The EQS is set on biota based on risk to human health from consuming fishery products.

⁶² The final report of the workshop is publicly available: <https://circabc.europa.eu/ui/group/65764c73-4a57-45dc-8199-473014cf65bf/library/34012063-b0e8-4630-b221-19ddc6e81d28/details>

⁶³ The final report is publicly available: <https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/a547839e-c8ef-4a0d-b4f5-0cb877cdd17e/details>

⁶⁴ PFBS, PFHxS, PFOS, PFBA, PFPA, PFHxA, PFHpA, PFOA, PFNA, PFDA.

⁶⁵ Directive 2008/105/EC amended by 2013/39/EC.

When an analytical method is available, **“PFAS total” could be listed in the WFD and EQS set**. Specific PFAS identified as SVHCs (e.g, PBT, vPvB, substances of equivalent level of concern) and key PFAS often found in the environment could consequently be **identified as priority hazardous substances**.

Analytical methods for water

In addition to the specific water legislations, **the work on analytical methods** would also benefit initiatives under the chemicals legislation. As explained in chapter 4, work is needed for the development of analytical guidelines for measuring “PFAS total” and groups of PFAS, including detection limits and parametric values. This work could cover methods that are already available, such as total organic fluorine. Updated guidelines could cover not only water, but also other environmental matrices, use in products to be regulated in the REACH restriction and in food, in order to allow the implementation and enforcement of the other actions on PFAS. Funding for such work could be provided via the EU budget for Research and Innovation (see chapter 10).

7. Horizontal products legislation

PFAS are used and/or present in many products, including for consumer use. The planned REACH restriction intends to cover all uses; however, it will take some time before it is implemented. Meanwhile, better traceability of the presence of PFAS in products could be an advantage, considering that one of the objectives of the Circular Economy Action Plan (CEAP)⁶⁶ is to address the presence of hazardous chemicals in products. PFAS are used in many of the priority categories for action of the CEAP (textiles, construction products, electronics, packaging and plastic). Traceability, trusted and verifiable information on the presence of PFAS in products would help consumers in their choices and could be used for Green Public Procurement as well as waste management and recycling.

One possible solution could be to **extend the EU Ecolabel requirements** to exclude the use of all PFAS in the various products categories for which EU Ecolabel criteria exist, where PFAS could be used and/or present, whenever possible and feasible.

The **sustainable products initiative** is another framework that could be used for including minimum information requirements on PFAS content for consumers/supply chain/public authorities. The presence of PFAS in products could be addressed through **generic principles** (i.e. for categories of products or all products) or **product specific requirements**.

8. Food legislation

Food can become contaminated with PFAS mainly through contaminated soil and water used to grow the food, through the concentration of these substances in animals via feed and water

⁶⁶ https://ec.europa.eu/environment/circular-economy/pdf/new_circular_economy_action_plan.pdf

and also through PFAS-containing food contact materials, such as food packaging or food processing equipment.

Maximum levels for contaminants in food are set under Regulation (EC) No 1881/2006 on the basis of the ALARA principle (as low as reasonably achievable). In 2008, the European Food Safety Authority (EFSA) carried out a risk assessment by deriving Tolerable Daily Intake values (TDI) for PFOS, PFOA and their salts⁶⁷. In 2018, EFSA proposed to lower the TDI for PFOS and PFOA⁶⁸. In 2020, EFSA updated its risk assessment for PFOS and PFOA and carried out a risk assessment for the sum of PFOS, PFOA, PFNA and PFHxS. The EFSA opinion⁶⁹ could serve as a basis to **set maximum levels** for the assessed PFAS substances in food.

9. The Industrial Emissions directive and European Pollutant Release and Transfer Register (E-PRTR)

Industrial Emissions Directive

Directive 2010/75/EU of the European Parliament and the Council on industrial emissions (the Industrial Emissions Directive or IED) is the main EU instrument regulating pollutant emissions from large industrial installations, including emissions of PFAS from sites where they are produced or used. Industrial activities listed in Annex I of the IED are required to operate in accordance with a permit (granted by the competent authorities in the Member States), if they exceed stated production thresholds. Some of these activities produce or use PFAS. Sector 4 of Annex I covers the chemical industry⁷⁰, including the facilities that are currently producing PFAS.

However, releases of PFAS into the environment can also occur during the manufacture of products where PFAS are used. Some of these activities are also listed in the IED's Annex I: e.g. surface treatment of metals, production of plant protection products, biocide and pharmaceuticals, production of textiles, leather tanning, production of pulp, paper, cardboard and wooden panels.

IED permits are based on the Best Available Techniques (BAT) described in BAT Reference Documents (BREFs). The Commission adopts the BAT conclusions (as Implementing Decisions) and Member States use them as a reference to define the permit conditions. In particular, the BAT associated emission levels (BAT-AELs) stated in BAT conclusions must not be exceeded when competent authorities set Emission Limits Values (ELVs) in permits.

⁶⁷ <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2008.653>

⁶⁸ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5194#>

⁶⁹ <https://www.efsa.europa.eu/en/news/pfas-food-efsa-assesses-risks-and-sets-tolerable-intake>

⁷⁰ The parts of Annex I sector 4 that are relevant for PFAS are:

- 4.1 Production of organic chemicals such as...
- (f) halogenic hydrocarbons,...
- (h) plastic materials (polymers, synthetic fibres and cellulose-based fibres), ...
- (k) surface-active agents and surfactants.
- 4.4 Production of plant protection products or of biocides
- 4.5. Production of pharmaceutical products including intermediates

Considering the persistence and mobility of PFAS in the environment, the objective should be to prevent or minimise emissions.

Annex II of the IED lists the polluting substances for which Emission Limit Values (ELVs) must be set in the permits and it indirectly covers some PFAS⁷¹. In addition, Article 14(1)a of the IED requires emission limit values to be set in permits “*for other polluting substances, which are likely to be emitted from the installation concerned in significant quantities, having regard to their nature and their potential to transfer pollution from one medium to another*”.

Waste treatment facilities are covered by the IED and these can emit PFAS. The BAT conclusions for waste treatment⁷² address PFOA and PFOS, but not other PFAS. Permits given to waste treatment plants have to implement the obligations within four years of BAT conclusion publication. Authorities can consider emissions limits for all other PFAS as well as for PFOS and PFOA.

Based on this, there is scope to better **address PFAS as a chemical class under the IED**. There are various ways to achieve this objective.

In order to ensure that the IED covers the most polluting industrial activities, there may be a need to **revise the IED’s sectoral scope**. The review of the IED will also assess whether further measures are required to address chemicals of concern such as PFAS and the need for BAT-AELs and / or specific technical requirements (e.g. closed circuit manufacturing and PFAS substitution).

When relevant BREFs are reviewed, they could be updated to address PFAS if they are identified as a Key Environmental Issue for that industrial sector. This may result in **identifying their use as non-BAT** and **setting BAT-AELs for relevant environmental compartments**. As part of the rolling review programme of BREF, the review of the textile industries BREF has already started⁷³.

European Pollutant Release and Transfer Register

The European Pollutant Release and Transfer Register (E-PRTR)⁷⁴ makes public accessible emission data reported by Member States on major industrial activities. It covers emissions from the activities defined in Annex I of the E-PRTR Regulation⁷⁵, which largely equates to Annex I of the IED. Some of these activities are sources of PFAS (chemical industry, surface treatment of metals, waste and waste water management, production of textile and leather). The recently completed ‘Review of E-PRTR implementation and related guidance’⁷⁶ recommended adding to the E-PRTR reporting requirements for PFHxS, PFOS and PFOA (including their salts and precursors). Reporting of PFAS emissions would increase the knowledge on the release sources, enabling an identification of potential contaminated sites.

⁷¹ Annex I includes PFOS, as it is listed as a priority hazardous substance in the WFD, and PFAS identified as CMRs and PBTs.

⁷² Commission Implementing Decision 2018/1147 of 10 August 2018.

⁷³ <https://eippcb.jrc.ec.europa.eu/reference/textiles-industry>

⁷⁴ <https://prtr.ec.europa.eu/> <https://prtr.eea.europa.eu/#/home>

⁷⁵ <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1583400375088&uri=CELEX:32006R0166>

⁷⁶ [Review of E-PRTR implementation and related guidance](#) (in Tables 3.1 and 3.2).

The upcoming Impact Assessment for the review of the E-PRTR Regulation could provide an opportunity to **include relevant PFAS**, going beyond PFHxS, PFOA and PFOS⁷⁷. It could also consider the possibility of **requiring the reporting of emissions of the whole family of PFAS**⁷⁸.

10. Waste legislations

PFAS are present as contaminants in waste from their production and use as well as in waste from waste management activities. They can be present in sludge from the treatment of industrial and urban wastewater, in landfill leachate and in emissions from incineration facilities. Waste treatment plants are covered by the IED presented in chapter 9.

Sewage sludge can be an important source of emissions of PFAS to the environment, when it is applied on land for use in agriculture. The Sewage Sludge Directive⁷⁹ regulates the use of sewage sludge in agriculture also by setting limits on the presence of heavy metals, but not of organic contaminants.

The Waste Framework Directive⁸⁰ contains specific provisions for hazardous waste. The classification of a waste as hazardous requires that it exhibits one or more of the hazardous properties listed in the Directive. In practice, this is estimated on the basis of the hazard classification of the substances it contains and on their concentration in the waste. Only few PFAS, e.g. PFOA, PFOS and some other long-chain PFAS, have a harmonised hazard classification under the Regulation on classification, labelling and packaging of substances and mixtures (CLP)⁸¹. However, there are some proposals for classification of additional PFAS under CLP⁸² that could in the future lead to the classification as hazardous of wastes containing them.

PFOA and PFOS are identified as POPs under the Stockholm Convention. In the EU, the provisions of the POPs Regulation⁸³ on environmentally sound management of wastes containing POPs apply. Moreover, under the Basel Convention, the Parties have developed technical guidelines on environmental sound management of POPs wastes. The guideline on wastes consisting of, containing or contaminated with PFOS, its salts and perfluorooctane sulfonyl fluoride (PFSF), is currently under review to include PFOA, its salts and PFOA related compounds.

The results of the **evaluation** of the **Sewage Sludge Directive**, to be launched soon, and the results of subsequent studies could provide the opportunity to **introduce limits for organic**

⁷⁷ The use of the list of 20 PFAS included in the Drinking Water Directive could be considered.

⁷⁸ Until an analytical method for “total PFAS” is available, a parameter such as “Total Organic Fluorine” could be considered.

⁷⁹ Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture.

⁸⁰ Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste.

⁸¹ Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures.

⁸² <https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18333861c>

<https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18333861c>

⁸³ Regulation (EU) of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

contaminants such as PFAS in the event of the review of the Directive, including the possibility to have a limit for “total PFAS” and/or for a group of specific PFAS.

The EU works with the Member States and all Parties to the **Basel Convention** in the development and review of guidelines for **sound management of POP waste**. The European Commission will work in the adaptation of the relevant guidelines following any future listing of PFAS substances as POPs.

As indicated in the new CEAP, the Commission will amend **Annex IV of the POPs Regulation** and is considering the introduction of a **limit value for PFOA** and the possible review of the value for PFOS.

The classification of PFAS substances under CLP has immediate effects on the classification of waste containing these substances. Developments under **GHS and CLP** relevant for PFAS could result in the need to **further align the waste legislation with CLP**.

11. Land and soil

There are many examples of soils contaminated with PFAS in the EU⁸⁴, often sites where fluorinated fire-fighting foams have been used, for training or to extinguish a fire (e.g. local fire stations, training centres, civil and military airports, etc.). Other cases of contamination include industrial sites where PFAS were produced or used (e.g. industries producing metals, semi-conductors, paper, textile, coatings, hydraulic fluids, etc.), landfills (e.g. containing carpets, clothes, furniture, cooking equipment, etc.) and wastewater treatment plants. Additional sources of diffuse soil pollution can be deposition from the atmosphere of PFAS emitted during production, waste incineration, use in plant protection products or biocides, and the application to soil of sewage or industrial sludge.

Being mobile and resistant to biodegradation, PFAS can move from the soil to contaminate groundwater and surface water and this has happened in many of the cases discovered in the EU. Soils contaminated with PFAS are usually excavated and disposed of in landfills. When the contamination has reached the groundwater, the remediation using filters is very long and costly⁸⁵. The short chain PFAS, used to substitute the long chain ones after they started to be regulated, are more difficult to remove from soil and water, as many of the conventional treatments are not effective⁸⁶. The carbon-fluorine bond can be broken only by thermal treatment of the soil at very high temperatures, at considerable costs.

Unlike for other environmental compartments, there is no dedicated European legislation on soil quality. For large industrial sites, there are provisions in the IED that relate to soil /

⁸⁴ Nordic Council of Ministers (2019), *The cost of inaction*, chapter 4 « The case studies »

⁸⁵ Data on the costs for the Veneto contamination case are available on *The cost of inaction*, chapter 4 « The case studies »

⁸⁶ Ross et al. (2018), *A review of emerging technologies for remediation of PFASs*

groundwater protection and remediation. More generally, the Environmental Liability Directive⁸⁷ establishes a framework for preventing and remedying environmental damage.

Member States can set their own rules and standards, but only very few have defined limit values for PFAS in soil. The Netherlands recently introduced PFAS limits for the re-use of excavated soil and sediment, but this has led to heavy debate because these new rules were considered too strict and were slowing down construction and dredging activities. Several Member States such as Belgium, the Netherlands and Germany have started measuring the background concentration of PFAS in soils, identifying the main sources of PFAS contamination and developing guidance and standards. The shared challenge to deal with the legacy of PFAS and other chemicals of emerging concern was also the reason why the Flemish authorities have recently set up an international network for emerging contaminants in soils (EmConSoil).

The **EU expert group on soil protection** could consider how **soil contamination from PFAS** can be addressed at EU level with a targeted and proportionate risk-based approach within a binding legal framework. They could also exchange knowledge and experiences on the safe, sustainable and circular re-use of excavated soil. This would allow to build further on the experience and knowledge of Member States in tackling PFAS in soils (e.g. ongoing work in Germany, Italy, Netherlands and Belgium). The **Zero Pollution Action Plan** and the revision of the **thematic strategy for soil protection** could also provide a framework to address the concerns raised by PFAS contamination of soils.

12. International dimension (OECD, Stockholm and Rotterdam Convention, UN-GHS)

PFAS are discussed at international level because of their potential for long-range transport.

The **OECD** has been working for some years to exchange information on PFAS, with the objective to support a global transition towards safer alternatives⁸⁸. In this framework, a key activity has been the development of the database of PFAS⁸⁹. **Active EU involvement in this work** helps to inform other OECD countries of its initiatives and approaches to address PFAS concerns.

The UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) is the international system that aims at harmonising hazard classification of chemicals, labelling requirements and safety data sheets requirements. Similarly to ozone depleting substances, the concern of substances that can contaminate natural resources due to their persistence and mobility could be addressed with a **new hazard class** developed under the **UN GHS system** and/or the **CLP Regulation**.

⁸⁷ Directive 2004/34/EC

⁸⁸ <https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/>

⁸⁹ [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV-JM-MONO\(2018\)7&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV-JM-MONO(2018)7&doclanguage=en)

Some PFAS are already listed in the annexes of the Stockholm Convention⁹⁰ on Persistent Organic Pollutants (POPs) and of the Rotterdam Convention⁹¹ on the international trade of certain hazardous chemicals. **Continuously proposing and supporting the listing of relevant PFAS in the Stockholm and Rotterdam Conventions** is one way to avoid emissions from PFAS regulated in the EU but not yet internationally and to control their trade, considering the outcome of the on-going and future EU restriction processes.

13. Research and innovation

To address the concerns of PFAS, targeted research and innovation activities could facilitate the implementation of regulatory actions. These activities relate to analytical methods (both screening methods for “total PFAS” and methods in various matrices for individual/groups of PFAS), alternative substances and technologies, remediation of contaminated soil and water, monitoring of emissions and fate in the different environmental compartments (including at the waste stage), human health effects and biomonitoring.

To this end, the Commission proposed a **specific topic on persistent and mobile chemicals under the EU Green Deal call** (WP2020 – projects to be selected for funding in 2021)⁹², with the objective to focus on the following key aspects for PFAS:

- Research and development of (bio)remediation technologies of contaminated soil and water for persistent and mobile substances, including sources of drinking water for persistent and mobile chemicals;
- Development of new cost-effective high-resolution methods to measure and separate persistent and mobile chemicals in different media;
- Environmental and human (bio)monitoring of persistent and mobile chemicals; gathering of toxicity and toxico-kinetic information in order to allow characterising all risks to human health, arising from the exposure to the entire group of these substances, including effects on the immune system;
- Development of best practices for the management of waste containing persistent and mobile substances; detection and identification of specific pollution problems.

Supporting the search for **alternatives to PFAS** could also be done through the next Framework Programme for Research and Innovation, **Horizon Europe**, under Cluster 3 “Digital and Industry”.

14. Conclusion

⁹⁰ <http://www.pops.int/>

⁹¹ <http://www.pic.int/>

⁹² Green Deal call “[Innovative, systemic zero-pollution solutions to protect health, environment and natural resources from persistent and mobile chemicals](#)”

The chemical class of PFAS poses concerns for human health and the environment because of their persistence and potential mobility, bioaccumulation and toxicity. PFAS will be present in the environment for a very long time, even if releases stopped immediately. Their emissions are also causing long-term accumulation in the environment and organisms, with increasing risks of harm. There are many examples of PFAS contamination of resources fundamental for human life, such as water and soil, with very high costs for society.

The regulation of individual or of groups of closely related PFAS has led to substitution with other PFAS, which are becoming an increasing concern. Their very high number makes it impossible to do a substance-by-substance assessment. Therefore, PFAS should be regulated as a chemical class, and initiatives going in this direction have started under the chemicals and the water legislations. PFAS should be addressed in other legislations as well, ideally in a coordinated approach, combining restrictions on production and use with control and reduction of emissions in the cases where they still need to be produced and used. The Annex to the Communication on a Chemicals Strategy for Sustainability presents the key actions to be taken by the European Commission on PFAS.

PFAS are widely used and some of these uses bring benefits to the society. Examples are medical devices and personal protective equipment for workers. The concept of essential uses – which has been proposed to be applied to PFAS - would help identify uses critical for society and allow them only if suitable alternatives are not available. Such an approach would lead to the development of alternatives and new business opportunities, especially if supported with Research and Development funding.