Elements for an EU-strategy for PFASs

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Summary - why action is needed now!

PFASs are a large family of thousands of man-made chemicals that are widely used throughout society. They are an increasing concern as they are resistant to degradation in the environment, very mobile, toxic and can bioaccumulate. They are also found everywhere in the environment.

They have been observed to contaminate water and soil in most EU countries and it is extremely costly to clean up such contamination. Without taking action now, their concentrations will continue to increase, and their toxic and polluting effects will be difficult to reverse.

Actions taken so far have not sufficiently addressed the concerns. This is why we urgently need a coherent and coordinated EU strategy to address PFASs through regulatory and non-regulatory actions. The goal is to minimise environmental and human exposure to PFASs, at all stages of their life cycle.

To achieve this:

(i) PFASs need to be **managed as a group.**
(ii) PFASs need to be **phased out** and only essential uses allowed until alternatives are available.
(iii) **Limit values** need to be set in different pieces of legislation.
(iv) Steps to ensure **effective enforcement** are needed.
(v) **Environmental monitoring**, **awareness raising**, **research on alternatives**, **remediation** and **environmentally sound management of waste** are also needed.

The REACH Regulation is key for addressing concerns associated with the use of PFASs in the EU, but legal measures under other EU legislations as well as actions on a global level will substantially contribute to the goal of the strategy.

In line with the timeframe of the UN Global Goals for Sustainable Development, we propose that actions on the EU level to phase out PFASs should be taken at the latest by 2025, to be in effect by 2030.

Elements for an EU-strategy for PFASs

Why do we need to act?

PFASs (short for per- and polyfluoroalkyl substances) constitute a group of thousands man-made chemicals that are widely used in various technical applications in society due to their unique physical and chemical properties. Since they are chemically and thermally stable as well as repellent to water and oil, they are used in products such as water- and stain repellent textiles, fire-fighting foams, food contact materials (FCMs) and cosmetics. PFASs can give rise to environmental contamination throughout a product's life cycle, such as manufacture, end use, recycling, waste management and sewage treatment. Some PFASs can also be released from mixtures and articles that contain impurities of these substances. Goods contaminated with PFASs that have been manufactured outside of the EU and then imported are a growing source of PFASs.

Due to their extraordinary persistence, human and environmental exposure to PFASs will be a long-term source of concern. PFASs have been detected globally in human and wildlife biomonitoring studies e.g. in arctic polar bears. PFASs can also persist for years in humans once exposed and have been found in human breast milk and umbilical cord blood. Toxic effects on the liver is an indicative response to PFAS-exposure in several species, while the adverse effects also include effects on the lipid metabolism and the immune system.

Some PFASs, such as the well-known PFOA and PFOS, have been extensively investigated and regulated, while for many other PFASs there is still very limited or completely missing knowledge about their current uses and hazards. Some of the less known PFASs represent an emerging concern due to their high persistence and environmental mobility and wide-spread use in products. Contamination of water and soil by PFASs has already occurred in the EU and other parts of the world.[1] Therefore, PFASs have already generated significant remediation costs and such costs will increase as sites requiring decontamination continue to be identified.

Due to the problems and concerns caused by PFASs, there is a need for an EU-strategy that addresses all PFASs through regulatory and non-regulatory interventions and drives the work in a coherent direction. Several actors[2], including the European Parliament[3] have raised their concerns regarding exposure to PFASs and called for action. The European Commission has earlier pointed out the properties of PFASs as especially problematic.[4]

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[1] http://www.euro.who.int/__data/assets/pdf_file/0018/340704/FINAL_pfas-report-20170530-h1200.pdf

[2] For example the Helsingør Statement (Scheringer et al., 2014), Madrid Statement (Blum et al., 2015) and the Zürich Statement (Ritscher et al., 2018).

[3] Letter to Timmerman of 15 April, 2019. Subject: Your commitment to protect EU groundwater resources and citizens' health from PFAS contamination. Ref. Ares(2019)2656082 - 16/04/2019.

[4] Study for the strategy for a non-toxic environment of the 7th EAP. Sub-study d: Very Persistent Chemicals. EUROPEAN COMMISSION Directorate-General for Environment. August 2017. COM proposal for limit values in the Drinking Water Directive.

This paper argues for elements that should be included in an EU-strategy for PFASs with the goal to minimise environmental and human exposure to PFASs in all life cycle stages of the substances. To achieve this goal, PFASs should be managed as a group because of their similar properties of concern, large number of substances, and to avoid regrettable substitution. Therefore, only uses essential to society should be accepted and substitutes for these uses should be sought with urgency.

The REACH Regulation is a key regulation in EU for managing risks associated with the use of PFASs, but also other regulatory as well as non-regulatory instruments should be used and are described in Annex I of this document.

PFASs will remain in the environment for ages

All PFASs are, or ultimately transform into, persistent substances. For instance, according to UNEP[5], perfluorooctanoic acid (PFOA) does not undergo any further abiotic or biotic degradation under relevant environmental conditions. Substances that are transformed into stable PFASs are called PFAS-precursors or "related substances". The extreme persistence of PFASs leading to irreversible environmental exposure is a reason for major concern.

Due to their water solubility and mobility in soil, contamination of surface, ground-, and drinking water and soil has occurred in the EU and globally and will continue until action has been taken. It has been proven very difficult and extremely costly to remove PFASs when released to the environment. The Helsingør Statement[6], the Madrid Statement[7] and recently the Zürich Statement[8] have also supported this concern and a need for risk management.

PFASs cause harm

Some PFASs have been documented as toxic and/or bioaccumulative substances.[9] Knowledge about the hazards of PFASs is mostly based on data from toxicological studies in laboratory animals. Observed effects in laboratory animals after exposure to several PFASs include:

- Effects on the liver
- Decreased thyroid hormone levels
- Effects on lipid metabolism
- Development of tumours in one or several organs
- Immunotoxicity

[5] UNEP/POPS/POPRC.11/5 (2015) Proposal to list pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds in Annexes A, B and/or C. to the Stockholm Convention on Persistent Organic Pollutants. Persistent Organic Pollutants Review Committee Eleventh meeting, Rome, 19–23 October 2015.
[6] Scheringer et al. (2014). Helsingør Statement on poly- and perfluorinated alkyl substances (PFASs). Chemosphere 114:337-339.
[7] Blum et al. (2015). The Madrid Statement on Poly- and Perfluoroalkyl Substances. Environmental Health Perspectives 123(5): A107-A111.
[8] Ritscher et al. (2018). Zürich Statement on Future Actions on Per-and Polyfluoroalkyl Substances (PFASs). Environmental Health Perspectives 126(8) August 2018.
[9] For instance, PFOA, PFNA, PFDA, and PFHxS, are included in the Candidate List under the REACH Regulation as substances of very high concern due to their vPvB or PBT properties.

– Developmental toxicity

Based on the above findings, some PFASs are classified in the EU as toxic to reproduction, the liver and as suspected carcinogens.

Health effects in humans that have been associated with exposure to certain PFASs are:

– Increased cholesterol levels
– Impact on infant birth weights
– Effects on the immune system
– Increased risk for cancer
– Thyroid hormone disruption[10] [11]

Data are available for some PFASs, however based on similarities between PFASs, concerns are raised for the whole group. In addition, based on their similarities, combination effects of PFASs can be expected.

Regulatory challenges

In total, 4 730 PFAS-related CAS numbers have been identified.[12] A substance-by-substance evaluation of all these substances is therefore not practically possible. There are on-going assessments and regulations of a few sub-groups of PFASs via so-called "arrowhead substances"[13] (see Annex II). However, ECHA has estimated that 50-100 arrowhead substances need to be assessed to cover all PFASs, which is not possible within a reasonable timeframe. In addition, exposure to intermediate degradation products is not considered. Therefore, a new approach to address PFASs as a group is needed.

There are also other difficulties hindering detailed assessments of individual PFASs. For example, many PFASs:

i. lack CAS-number,
ii. have unclear composition,
iii. lack information on their properties and degradation products,
iv. are constituents of imported articles, which cannot be covered by other REACH measures than restriction, or
v. do not need to be registered under REACH if considered to be polymers or produced in volumes below the registration thresholds.

Although PFASs are widely used, the lack of information on their specific uses and toxicity makes it difficult to estimate the degree of exposure and the risks that PFASs pose for humans and the environment. However, the persistence of PFASs in

[10] https://www.efsa.europa.eu/en/efsajournal/pub/5194
[11] http://www.c8sciencepanel.org/
[12] 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). ENV/JM/MONO(2018)7. 4 May 2018.
[13] Sub-groups with a common degradation product, e.g. PFOA and substances that degrade to PFOA.

combination with other properties (bioaccumulation, mobility, long-range transport potential and toxicity of some PFASs) and irreversible contamination of the environment with partly unknown PFAS-mixtures make the case for urgent action.

Cost of inaction

Remediation and clean-up of PFASs, if at all possible, is very expensive and time consuming with substantial socio-economic impacts as a result. In a recent cost of inaction report[14] the societal costs for remediation of drinking water and groundwater[15] in Europe alone have been calculated to be at least 10-20 billion EURO over 20 years. These estimates do not include costs for *inter alia* ecological damage and loss of property value as these could not be quantified. These are best estimates of the aggregated costs for remediation but the true costs are potentially much higher. An estimate of the costs for one case of remediation (the town of Rastatt in Baden- Württemberg in Germany) was found to be approximately 1-3 billion EURO.

Although there is limited knowledge on the adverse effects of most PFASs, the cost of inaction report shows high health-related costs associated with exposure to known hazardous PFASs. The annual costs related to some adverse effects on human health were estimated to be even higher than the total cost for remediation.

The characteristics of PFASs and the potential health and environmental costs is a strong indication that the ongoing use of PFASs will result in a legacy problem in the future, both from an environmental, health and economical point of view. Thus, it is important to take immediate action to cease the release and exposure of all PFASs as far as possible. We therefore need a novel regulatory approach for this group.

The way forward

A successful strategy for addressing the problems with PFASs must focus on minimising the releases of PFASs to the environment and human exposure. This can be done by significantly reducing their production, use and import in articles, as well as by decreasing human exposure and emissions from past uses including the waste stage.

We propose that action should be taken at the EU-level to phase out PFASs at the latest by 2025, to be in effect by 2030. This is in line with the timeframe for the UN Global Goals for Sustainable Development.[16]

[14] The cost of inaction - A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS. TemaNord 2019:516. A publication funded by the Nordic Council of Ministers.
[15] In these aggregated costs, the costs for environmental screening, monitoring (where contamination is found), water treatment, soil remediation and health assessment were included.
[16] Sustainable Development Goal 3 - Ensure healthy lives and promote well-being for all at all ages: *"By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination."* https://sustainabledevelopment.un.org/sdg3

Several aspects need to be considered to manage PFASs. These should as far as possible be included in all relevant regulatory instruments and are considered below:

1) PFASs should be managed as a group

PFASs should be assessed and managed as a group for several reasons:

a) Regulating individual substances or arrowhead substances (subgroups) will take too long to effectively manage the risk from these substances.
b) All PFASs, in themselves or their degradation products, are extremely stable in the environment.
c) Some PFASs have documented toxicity. With the present knowledge, and based on similarities between PFASs, concerns are raised for the whole group.
d) Human and environmental exposure to many PFASs occur and combination effects can be expected.
e) A group approach is needed to avoid regrettable substitution. PFASs that are regulated are often replaced by similar, but not yet regulated, PFASs.

The boundaries of which substances are included in the PFAS-group are not sufficiently clear and need to be specified.

2) *Uses of PFASs should be limited to essential uses only*

The unique physical and chemical properties of PFASs have led to a wide range of uses in products for professionals and consumers. As a result, society has partly become dependent on these substances in some uses. However, due to known negative impacts on human health and the environment, and the irreversibility of contamination due to the extreme persistence, PFASs should only be allowed for essential uses. Any non-essential use should be phased out as soon as possible. For uses that are considered essential, all possible measures to minimise releases and exposure during the whole life cycle should be taken.

Essential uses must be clarified. A starting point could be the definition in the Montreal Protocol[17] and a recent scientific assessment of the concept[18]. Non-essential uses could be divided into different subgroups of uses with a stepwise approach for phase out. One approach could be to start regulating consumer uses, as these are more likely to be non-essential (e.g. clothing, cosmetics, toys and food contact materials). Thus, only uses necessary for health and safety or critical for the functioning of society should be allowed. Essential uses should be assessed with regard to the availability of alternatives on a regular basis to ensure future

[17] Decision IV/25 (4th Meeting of the Parties to the Montreal Protocol, 1992). Montreal Protocol on Substances that Deplete the Ozone Layer (a protocol to the Vienna Convention for the Protection of the Ozone Layer).
[18] Cousins et al. (2019). The concept of essential use for determining when uses of PFASs can be phased out. Environmental Science Processes & Impacts. DOI: 10.1039/c9em00163h.

replacement and phasing out of PFASs. Thus, essential uses that have been agreed upon should be regularly reviewed to ensure that alternatives are developed.

Actions

To achieve the strategy's goal to minimise environmental and human exposure to PFASs, actions are needed in several policy areas. Relevant regulatory measures to minimise production, import, use, emissions and exposure to PFASs and other actions are listed with bullet points in Annex I, without any ranking their importance. The proposed actions are based on what actions are expected to be most effective and efficient but also include ongoing and/or upcoming initiatives. Some actions are complementary, whereas others are alternatives to each other. Each action will need to be further specified and elaborated by the Commission in collaboration with other actors (e.g. EU Agencies and Member States). In addition, consultation with the industry is important when developing new regulation. Industry should take more responsibility and take voluntary initiatives to phase out PFASs. A successful strategy will require all relevant actors to work towards a common goal.

ANNEX I Examples of actions

Regulatory actions to minimise the production, import and use of PFASs

Overall, PFASs are produced in high quantities globally and widely used in various products. Actions to minimise their production, import and use can be taken under for example the REACH Regulation, the CLP regulation, regulations for Food Contact Materials (FCMs), the Cosmetics and the POPs Regulations. Some of these legislations consider only human health although environmental protection goals should also be considered. Nevertheless, any restriction of PFASs in product specific legislation that only considers protection of human health (e.g. Toy Safety Directive) will reduce the release of PFASs to the environment and thereby indirectly the exposure to humans via the environment. In addition, enforcement actions should be taken to check compliance with regard to particular obligations imposed by legislations to help manage PFAS-risks, where appropriate.

REACH

The REACH regulation ((EC) No 1907/2006) is the most extensive legislation for managing chemicals in the EU. It includes the four processes of registration, evaluation, authorisation and restriction of chemicals. REACH requires industry to register information for substances they produce or import into the EU at or above 1 t/a (registration). Data requirements are tonnage dependent. Based on this information substances may undergo evaluation and if found to be of concern they can either be banned with the opportunity to authorise specific uses (authorisation), and/or restricted with possible derogations for essential uses (restriction). No information is obtained from REACH for low tonnage PFASs (<1 t/a per producer/importer).

Registration

Polymers constitute a large group of PFASs. However, REACH does currently not specify any requirements for registration or evaluation of polymers (only monomers are covered).

According to Article 138(2) of REACH, the Commission may present legislative proposals when a practicable and cost-efficient way of selecting polymers for registration has been identified. Two studies have already been performed to look at registration requirements for polymers.[19] A new study is ongoing with the aim to identify which polymers should be registered/evaluated under REACH.[20] The registration/evaluation of some polymers would allow obtaining information on production volumes and intrinsic properties of the polymers but also on their

[19] 28th Meeting of Competent Authorities for REACH and CLP (CARACAL), CA Session, Brussels, 13/11/2018, Doc. CACS/47/2018.
[20] 28th Meeting of Competent Authorities for REACH and CLP (CARACAL), CA Session, Brussels, 13/11/2018, Doc. CACS/47/2018.

degradation products when necessary. Registration of polymers would be helpful for enforcement.

Authorisation

Inclusion in the REACH candidate list will trigger information requirements on PFASs in the supply chain and to consumers. Inclusion in the candidate list can also make PFASs subject to authorisation obligations. However, authorisation is not considered the preferred option for PFASs since it is a substance-based measure not covering imported articles. Inclusion in the candidate list can help to identify the properties of concern, but this may not be necessary for taking risk management actions.

- PFASs that by far exceed the trigger of being very persistent in combination with other intrinsic properties that are of concern, could be identified as SVHCs and included in the candidate list.

Restriction

Restriction is the most effective and efficient way to manage such a large and complex group of substances that are used in numerous of applications. In addition, a restriction can cover imported articles. A broad restriction is therefore preferable to authorisation.

- A broad restriction under REACH covering *all* PFASs would be the preferred option, in order to limit as many non-essential uses as practically possible. This would have the greatest impact on minimising human and environmental exposure to PFASs. A broad restriction would also include unknown PFASs and uses.
- Grouping PFASs on a sector-by-sector, together with arrowhead approach based on the largest contributions of PFASs to human and environmental exposure could also be considered. Preparatory work has already started that may lead to this approach for fire-fighting foams.[21]
- Consumer uses could be considered for a group wise general restriction. For example, it could be questioned why PFASs are needed in everyday consumer products and articles, e.g. textiles, food contact materials and cosmetics. These uses could therefore be assessed as non-essential and a first priority for a restriction.

Regulations on food contact materials (FCMs)

Grease- and water-repellent paper can contain PFASs. These materials are used as FCMs, such as popcorn bags, sandwich paper and other fast food paper wrapping. Materials that come into contact with food are regulated in Regulation (EC) No

[21] During 2019, the Commission and ECHA have started two projects on pre Annex XV dossier on PFASs in fire-fighting foams (More information on the project can be requested to the Commission). As a first step, two parallel studies have been launched to gather information on the presence of PFASs and alternatives to PFASs in fire-fighting foams. The use of PFASs in textiles is a subject of a next study, as a first step towards an Annex XV dossier on PFASs in textiles.

1935/2004. This is the EU Framework Regulation, which among others provides the general principles for ensuring the safety to human health of all FCM.

Specific measures for materials listed in Annex I to the Framework Regulation can be adopted and exist among others for plastic material and articles that come into contact with food (Regulation (EC) No 10/2011[22]). The regulation contains a list of substances that are approved for use in plastic FCM (the so-called "Union positive list"). Several PFASs, including the ammonium salts of PFOA[23], are included on the positive list and thus allowed for use under certain conditions in plastic FCM. The purpose of these conditions is to ensure that FCMs do not cause migration of fluorinated substances in amounts that can endanger human health.

Considering the environmental concerns regarding PFASs, they should not be used in FCMs. Most PFASs used in FCMs will be degraded to extremely persistent and potentially toxic perfluorinated carboxylic acids similar (or identical) to PFOA, for which EFSA recently has suggested a very low limit value. In addition, EFSA is currently assessing more PFASs.

- Phase out the use of *all* PFASs in *all* types of FCMs. This could be regulated through specific measures under the Framework Regulation (EC) No 1935/2004 or by a restriction under REACH.
- PFASs should be removed from the list of permitted substances in plastic material intended to come into contact with food (Regulation (EC) No 10/2011).

Cosmetics regulation

PFASs are used in various cosmetic products. The EU regulation on cosmetic products aims to protect consumers from health risks associated with the use of cosmetics.[24] Risks to the environment are excluded. This Regulation lists substances that are not allowed in cosmetic products and substances that may be used under certain conditions. Substances prohibited in cosmetics products are for a major part CMR-substances and listed in Annex II of 1223/2009 and substances subject to restrictions are listed in Annex III. In order to restrict all PFASs in cosmetics products under regulation 1223/2009, all PFASs must be added to Annexes II or III substance by substance, which might be unfeasible.

- Phase out the use of *all* PFASs in cosmetic products considered non-essential use. This can be done under REACH (based on environmental concern) or under the Cosmetics Regulation (based on health hazard concern).

[22] The European Commission's Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food.
[23] CAS 3825-26-1.
[24] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

Regulations on plant protection and biocidal products

Co-formulants used in or mixed with plant protection products can contain PFASs, mainly in the function of wetting agents. The application of plant protection products containing PFASs results in a direct contamination of the arable land and the environment. Annex III of Regulation (EC) No 1107/2009[25] lists co-formulants not accepted for use in plant protection products. Up to now, Annex III has no entries but there is a Commission proposal for Annex III focusing mainly on substances regulated under REACH.

- Phase out the use of *all* PFASs as co-formulants in plant protection products. The most efficient implementation would be to list in general PFASs as unacceptable co-formulants in Annex III (Regulation (EC) No 1107/2009). According to the current Annex III proposal, unacceptable co-formulants would include PFASs identified as SVHC or restricted under REACH.

  Because plant protection products are often used for non-agricultural purposes e.g. for home pest control, PFASs may also be present in biocides. PFASs should not be permitted for use in biocidal products.

POPs Regulation (Stockholm Convention) and other international fora

The Stockholm Convention on Persistent Organic Pollutants is one of the main instruments for regulating chemicals globally. The Convention has been implemented in EU through the POPs Regulation[26].

- Nominate PFASs or groups of PFASs under the Stockholm Convention for global phase-out.
- OECD/UN should be encouraged to invite its members to work together more actively on PFASs and to phase out the use of PFASs globally.

Regulatory actions to minimise exposure to PFASs in the workplace and from the environment.

Limiting as far as possible the production and use of PFASs needs to be accompanied by minimising emissions to the environment and human exposure to PFASs. Actions to minimise exposure can be taken under several EU legislations covering different parts of a product's life cycle. For example, the Occupational, Health and Safety legislation (OHS), the Industrial Emission Directive (IED), the Waste Framework Directive, the Water Framework Directive (WFD) and the Sewage Sludge Directive. Examples of different regulatory actions are described below.

Regulation of contaminants in food.

When required for the protection of public health, on the basis of Regulation (EEC) No 315/93, maximum levels for contaminants in food are set under Regulation (EC) No 1881/2006 at levels which are as low as reasonably achievable. EFSA is currently

[25] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market.
[26] Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC.

carrying out a risk assessment for PFASs in food. On the basis of this assessment, discussions will be started on the possible need to set maximum levels for PFASs in food.

Water Framework Directive (WFD)

Since many PFASs are water-soluble and mobile in soil there is a risk of further adding to the contamination of drinking water supplies which will persist for a long time. The EU WFD[27] aims to ensure that all European waters are in good condition by a set date and protects water based on natural geographical formations, e.g. river basins instead of administrative or political boundaries. The WFD is complemented by other, more specific EU legislation, e.g. the Directive on Environmental Quality Standards (2008/105/EC amended by 2013/39/EC) in the field of water policy, the Ground Water Directive (2006/118/EEC) and the Drinking Water Directive (98/83/EC). Perfluorooctane sulfonic acid (PFOS) is the only PFASs currently listed as a priority hazardous substance in the EQS-directive with environmental quality standards (EQS) that are used to establish chemical status.

- In view of the need to prevent further emissions of PFASs to water bodies, a new EQS for the overall concentration of PFASs should be included in the Directive on Environmental Quality Standards.
- New limit values for PFASs in the Drinking Water Directive should include a limit value for the overall concentration of PFASs as well as a limit value for the sum of selected PFASs.
- There is a need to coordinate the working processes in the Drinking Water Directive and at EFSA[28] so that limit values for drinking water and food are coherent.
- PFASs as a group should be included in the Groundwater Directive and limit values should be set in the ongoing Water Framework Directive fitness check process and groundwater voluntary watch list process.
- As proposed in Art 16 (9) "strategies against pollution of water" of the WFD, it might be suggested that the European Commission is preparing a strategy against pollution of water by PFASs.

Industrial Emissions Directive (IED)

At industrial sites where PFASs are used, handled or produced, it is important to ensure that PFASs are not released to the environment to prevent pollution (e.g. in soil and groundwater) or exposure to workers. The IED is the main EU instrument regulating pollutant emissions from industrial installations. As far as PFASs are listed in Annex VI in the CLP-regulation ((EC) No 1272/2008), i.e. have a harmonised classification, they have to be addressed in the baseline report as relevant hazardous substances.

Installations undertaking the industrial activities listed in the IED are required to operate in agreement with a permit granted by the competent authorities in the

[27] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy.
[28] 23 PFASs are being assessed currently.

Member States. Permits under IED must consider the whole environmental performance of the plant, which includes emissions to air, water and soil, generation of waste, prevention of accidents, and restoration of the site upon closure.

It is not mandatory for PFASs to be included in the CLP (Annex VI) in order to be addressed in BREFs[29] or in IED permits. Other criteria such as, the quantity of emissions, the impact to the environment and health, the potential for identifying a technique to reduce the pollution etc. play a role. However if a substance is classified as hazardous and included in CLP (Annex VI) this will be helpful for the regulation of IED sites.

- At industrial sites where use or production of PFASs occurs, PFASs should be included in the IED permits with the aim to minimise release of PFASs to the environment. However, it is currently not feasible to address all industrial sectors, installations and usages of PFASs in the IED. Having more PFASs classified under the CLP regulation will result in more substances assessed under the IED.

Waste legislation and management

PFASs are known contaminants during waste management, e.g. there might be leachate of PFASs from landfills and dumpsites. However, PFASs are not addressed specifically in the European Waste Framework Directive and relevant waste legislation (such as establishing criteria and procedures for the acceptance of waste at landfills[30]). In principle, leachate and process water from waste treatment have to fulfil specific national wastewater legislation. In addition, indirect discharges to water bodies via public wastewater treatment plants occur and there are additional legislative obligations[31].

Waste treatment plants covered by the scope of the IED have to ensure that best available techniques (BAT) for the waste treatment sector[32] are applied. PFOA and PFOS are addressed by the BAT Conclusions for monitoring of emissions to waste. The related obligations have to be taken up in permits given to relevant waste treatment plants within four years of the implementation of the IED. Authorities should consider to implement emissions limits for all other PFASs as well as for PFOS and PFOA.

- Member states should ensure that PFASs are fully included in the waste legislation.
- Limit values for PFASs should be set under the Sewage Sludge Directive (86/278/EEC) and in the future regulation on minimum requirements for water re-use.

[29] BAT (Best Available Techniques) Reference Document (BREF).
[30] Council Decision 2003/33/ECof 19 December 2002 establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to Directive 1999/31/EC.
[31] Reference to Waste Water Legislation.
[32] Commission Implementation Decision (EU) 2018/1147 of 10 August 2018 establishing best available techniques (BAT) conclusions for waste treatment, under Directive 2010/75/EU of the European Parliament and of the Council (notified under document C(2018) 5070).

Remediation of contaminated natural resources

Many contaminated sites concern training sites where PFOS-based fire-fighting foams have been used. This is often military or civil airports, but can sometimes be sites in communities contaminated by local fire brigades. PFASs, such as PFOS and PFHxS[33], can at these sites be found at high concentrations in the soil, and with time, they will also leach into the groundwater and surface water where they will enter the food chain.

Beside fire-fighting foams, industrial activities, discharge from municipal wastewater treatment plants as well as the use of pesticides, sewage sludge, or biocides contribute to elevated PFAS-levels in soil and water. Contamination of soil and water via atmospheric transport and deposition of anthropogenic PFASs may also contribute to a general contamination level.

There are currently no remediation methods that will efficiently clean soil in a cost-effective manner. Excavation and disposal at landfills are methods mainly used today. However, there is a risk that the contaminated soil may cause further pollution in new areas.

There are costly methods used to remove some PFASs from groundwater using a combination of simple filters and activated carbon filters. This method is used to purify groundwater and then pump the clean ground water into the groundwater aquifers, thereby very slowly decreasing the concentration of some PFASs in the ground water aquifers.

Contaminated groundwater used for drinking water production will result in contaminated drinking water. For some PFASs, efficient remediation techniques based on activated carbon filters are available for contaminated drinking water. However, those PFASs used today are still difficult, if at all possible, to remove from ground- or drinking water.

Contaminated drinking water is a source for human PFAS-uptake. Further, PFASs can be taken up by plants and crops, which is another entry route into the human food chain. Here, irrigation with PFAS-contaminated water can be an additional source for human exposure.

- Research on sources of PFASs to soil and water is urgently needed (as well as analytical methods to identify PFASs and precursors), e.g. by monitoring of air, soil and groundwater samples (particulate phase as well as air phase), entries via plant protection products, biocides, compost, sewages sludge, etc.
- Remediation methods for soil are needed.
- Treatment and disposal of contaminated soil should be regulated to avoid contaminated soil being shipped from contaminated sites to non-polluted areas. Guidance is needed for handling PFAS-contaminated soil, e.g. at landfills.
- Research is needed on how to efficiently and cost-effectively remove PFASs from groundwater and surface water.

[33] Perfluorohexane sulfonic acid.

Research, monitoring and information activities

Non-regulatory actions are necessary, besides regulatory instruments, to achieve the goal with the proposed elements for a strategy. For example, it is important to make the general public aware about the problems with PFASs so that they can make informed good choices. Research is another area where actions are needed. In addition, analytical methods to monitor PFASs in the environment and enforcement should be developed further and standardised.

Awareness raising

The problems that PFASs may cause to the environment and human health need to be communicated to initiate behavioural changes.

- Launch awareness raising campaigns to inform the general public, relevant authorities, and policy-makers on the problems associated with PFASs and available alternatives to PFASs.
- Strengthen existing Ecolabels so that PFAS-free products can be labelled as PFAS-free.
- International joint actions under e.g. OECD/UNEP Global PFC Group and SAICM.

Research on alternatives

To be able to replace PFASs there is a need for alternative chemicals or technologies. Even though there has been a development of fluorine-free alternatives, it can be difficult to find alternatives for essential uses where a very low surface tension or durable grease-repellent properties are necessary.

In addition, alternative technologies can be introduced and replace PFASs without any need for other chemicals.

- Facilitate research and promote existing alternative chemicals to PFASs and on new technologies that eliminate current PFAS-use.
- Encourage industry to take voluntary measures to limit use, releases and exposure to PFASs.
- Where alternatives are not available, and where use of PFASs are deemed essential, industry should provide toxicity data to support safe use.

Research on the fate and transport of PFASs in the waste stage

Release of PFASs occurs during all life cycle stages, one important is the waste stage. However, information on PFASs in generated waste and potential release to the environment from the waste management process is often inadequate. Research in the following areas is considered particularly relevant and should be facilitated:

- The origins, fate and transport of PFASs from wastewater treatment plants (incl. disposable waste), incinerators, landfills, as well as from recycling.
- The fate of PFASs coming from diffuse and hotspot sources in agricultural settings. This includes research on transfer of PFASs into food and occurrence of PFASs in food of vegetable and animal origin.

- Fate and transport modelling approaches should be further developed and used to support policy scenarios.

Monitoring – environment and humans

There is a need for long-term monitoring of PFASs as a group and to monitor risk-reducing measures that have been implemented. Environmental monitoring of several different PFASs is performed today. However, there is no standardised method for monitoring total PFASs concentration.[34] These methods are today used as a screening tool to determine if PFASs are present in different matrices and can be combined with targeted analytical methods.

- Member states are encouraged to share their monitoring data, via e.g. IPCheM[35].
- A standardised method should be developed for monitoring total PFASs concentration with a low detection limit in various matrices including food, products and human blood.
- Standardised analytical methods by CEN for PFASs need to be developed for enforcement to assure compliance with legislation.

A substantial number of existing PFASs are marketed without CAS number. This causes problems of identification, as the naming of substances in this group is very variable. Studies have demonstrated that it is often difficult to identify and categorize PFASs.[36] Lack of proper identification also makes it difficult to develop the analytical methods that are needed to monitor relevant PFASs in products, the environment and humans. Therefore, it is important that PFASs are properly identified with CAS numbers and are given informative substance names by the manufactures.

- Producers of PFASs should share information on the chemical identity of their substances, including impurities, synthesis methods, and analytical methods. Standard analytical methods should be developed to measure PFASs.

[34] Organic fluorine (TOF) or total oxidizable precursors (TOP).[34] However, TOF/TOP methods are currently not the preferred method for measuring compliance with restrictions on PFASs. This is because they catch all organic fluorinated molecules and not only the regulated.
[35] https://ec.europa.eu/jrc/en/event/conference/ipchem
[36] 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). ENV/JM/MONO(2018)7. 4 May 2018.
Swedish Chemicals Agency, 2015. Occurrence and use of highly fluorinated substances and alternatives - Report from a government assignment. Report 7/15.
https://www.kemi.se/publikationer/rapporter

ANNEX II On-going and completed activities as of 7 June 2019

Table 1 Completed/On-going activities

Activity	**Regulation**	**Status**
Classification	CLH Harmonised classification & labelling	Work completed for 6 arrowhead substances and 1 arrowhead substances is in the pipeline for Registry of intentions and opinion-forming/decision-making.
Substance Evaluation	REACH	18 PFASs are currently being assessed.
Assessment as potentially EDs or PBTs	REACH	6 PFASs are under assessment.
Identification as an SVHC	REACH	Work completed for 3 arrowhead substances[37]. 2 arrowhead substances are in pipeline for Registry of intentions and opinion-forming/decision-making.
Restriction	REACH	Work completed for 1 arrowhead substance[38] (PFOA) and 8 arrowhead substances are in pipeline for Registry of intentions and/or opinion-forming/decision-making.
Limit values for the PFASs	Drinking Water Directive	
	Groundwater Directive	The potential inclusion of PFASs in Annex I or II of the Groundwater Directive will be subject to the outcomes of the Water Framework

[37] Includes the grouping C9-C14 PFCAs.

[38] Having a restriction for an arrowhead substance means that precusors/related substances are also included in the restriction.

		Directive fitness check process and the groundwater voluntary watch list process.
Studies on PFASs in fire-fighting foams	REACH	The Commission and ECHA are working on two parallel studies to gather information on the presence and alternatives to PFASs in fire-fighting foams.
Study on PFASs in textiles	REACH	The Commission will launch a study on PFASs in textiles in July.
Polymers	REACH	An ongoing study with the aim to identify which polymers could be subject to registration/evaluation under REACH. The registration/evaluation of some polymers would allow obtaining information on the intrinsic properties of the polymers but also on their degradation products, like some PFASs, when necessary.
Research funding		Biomonitoring under the HBM4EU project. HBM4EU is a joint effort of 28 countries, the European Environment Agency and the European Commission, co-funded under Horizon 2020. The project started in 2017 and runs until 2021. The aim of the project is to advance human biomonitoring in Europe by developing methods and databases. The focus is on collecting data on human biomonitoring and coordinating monitoring campaigns.
Global phase-out	Stockholm Convention	PFOS and PFOS-related substances - Removing most of the exemptions for acceptable purpose or to convert them to specific exemptions.

		PFOA, its salts and PFOA-related compounds - Listing in Annex A. PFHxS - Adopted risk profile
Risk management	OECD	Potential opportunities for further work at OECD on the risk management of Per- and Polyfluorinated Alkyl Substances. See report from the 59th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. 10 April 2019.