OSPAR COMMISSION

Background document for per- and polyfluoroalkyl substances (PFAS)

Hazardous Substances and Eutrophication Series

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OSPAR Convention

The Convention for the Protection of the Marine Environment of the North-East Atlantic (the "OSPAR Convention") was opened for signature at the Ministerial Meeting of the former Oslo and Paris Commissions in Paris on 22 September 1992. The Convention entered into force on 25 March 1998. The Contracting Parties are Belgium, Denmark, the European Union, Finland, France, Germany, Iceland, Ireland, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom

Convention OSPAR

La Convention pour la protection du milieu marin de l´Atlantique du Nord-Est, dite Convention OSPAR, a été ouverte à la signature à la réunion ministérielle des anciennes Commissions d´Oslo et de Paris, à Paris le 22 septembre 1992. La Convention est entrée en vigueur le 25 mars 1998. Les Parties contractantes sont l´Allemagne, la Belgique, le Danemark, l´Espagne, la Finlande, la France, l´Irlande, l´Islande, le Luxembourg, la Norvège, les Pays-Bas, le Portugal, le Royaume-Uni de Grande Bretagne et d´Irlande du Nord, la Suède, la Suisse et l´Union Européenne.

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Executive Summary

Per- and polyfluoroalkyl substances (PFAS) are a large group of chemicals, which have been widely used in industrial and household appliances since the 1950s. PFAS are defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it). All PFAS under this definition are covered by the entry of PFAS on the list of substances for priority action (LCPA).

The PFAS found in the environment have multiple sources, dependent on the emission of the specific substance and its precursors. The total PFAS production in the EU has been estimated to be approximately 75 000 tonnes/year. The emissions to water from paper mills alone have been estimated to be between 11 000 and 28 000 tonnes/year.

Due to their water solubility and mobility, contamination of water, soil and biota has occurred globally. The bond between fluor and carbon is the strongest chemical bond known in organic chemistry, which makes PFAS very persistent This is supported by monitoring data on air, water, sediment and documenting its spatial-temporal distribution in most compartments of the environment.

This background document has summarised the work presented in the draft EQS dossier proposed to the EU. From existing evaluations, it is known that PFOS, PFOA and other PFAS have a relatively low acute toxicity to water organisms, but they may pose a problem when entering the food chain via fish. Therefore, the analysis was mainly focused on deriving human health-based quality standards for fish consumption.

This report also summarises a recent and comprehensive review on PFAS in marine environment and biological effects. However, sufficient data to assess their environmental impact in only available for a limited number of PFAS, therefore, as a pragmatic approach, the current background document explains the validity for the selection of 24 PFAS for the purpose of monitoring and environmental risk assessment. Other PFAS than these 24 PFAS have been found to be present in the environment.

Actions are in place to tackle environmental PFAS emissions including WFD, MSFD, Stockholm convention, EFSA (EFSA 2020) and REACH with the goal to ensure high level protection of human health and the environment. This also aligns with the OSPAR operational objective S2.01 on identification of contaminants of emerging concern and priorities them for action.

Récapitulatif

Les substances per- et polyfluoroalkyles (PFAS) constituent un vaste groupe de produits chimiques largement utilisés dans les appareils industriels et ménagers depuis les années 1950. Les PFAS sont définis comme des substances fluorées qui contiennent au moins un atome de carbone méthyle ou méthylène entièrement fluoré (sans atome H/Cl/Br/I attaché). Toutes les PFAS répondant à cette définition sont couvertes par l'inscription des PFAS sur la liste des substances devant faire l'objet de mesures prioritaires (LCPA).

Les PFAS présents dans l'environnement ont des sources multiples, qui dépendent de l'émission de la substance spécifique et de ses précurseurs. La production totale de PFAS dans l'UE a été estimée à environ 75 000 tonnes par an. Les émissions dans l'eau provenant des seules papeteries ont été estimées entre 11 000 et 28 000 tonnes/an.

En raison de leur solubilité dans l'eau et de leur mobilité, la contamination de l'eau, du sol et du biote s'est produite dans le monde entier. La liaison entre le fluor et le carbone est la liaison chimique la plus forte connue en chimie organique, ce qui rend les PFAS très persistants. Ceci est confirmé par les données de

surveillance de l'air, de l'eau et des sédiments et par la documentation de leur distribution spatio-temporelle dans la plupart des compartiments de l'environnement.

Ce document de fond résume les travaux présentés dans le projet de dossier sur les NQE proposé à l'UE. Les évaluations existantes montrent que les SPFO, l'APFO et d'autres SPFO ont une toxicité aiguë relativement faible pour les organismes aquatiques, mais qu'ils peuvent poser un problème lorsqu'ils entrent dans la chaîne alimentaire par l'intermédiaire des poissons. C'est pourquoi l'analyse a été principalement axée sur l'élaboration de normes de qualité fondées sur la santé humaine pour la consommation de poisson.

Ce rapport résume également une étude récente et complète sur les PFAS dans l'environnement marin et leurs effets biologiques. Toutefois, on ne dispose de données suffisantes pour évaluer leur impact sur l'environnement que pour un nombre limité de PFAS. Par conséquent, dans le cadre d'une approche pragmatique, le présent document de référence explique la validité de la sélection de 24 PFAS à des fins de surveillance et d'évaluation des risques pour l'environnement. D'autres PFAS que ces 24 PFAS se sont révélés être présents dans l'environnement.

Des actions sont en place pour lutter contre les émissions de PFAS dans l'environnement, notamment la DCE, la DCSMM, la Convention de Stockholm, l'EFSA (EFSA 2020) et REACH, dans le but d'assurer un niveau élevé de protection de la santé humaine et de l'environnement. Ceci s'aligne également sur l'objectif opérationnel OSPAR S2.01 sur l'identification des contaminants de préoccupation émergente et leurs priorités d'action.

Background

Per- and polyfluoroalkyl substances (PFAS) are a large group of chemicals (>14,000), which have been widely used in industrial and household appliances since the 1950s.

PFAS consist of a fully (per) or partly (poly) fluorinated carbon chain connected to different functional groups. The length of the fluorinated carbon chain results in different physicochemical properties that influence the substance behaviour in the environment and in organisms, and its bioaccumulation and (eco) toxicity. PFAS are, or ultimately transform into, persistent substances. The bond between fluor and carbon is the strongest chemical bond known in organic chemistry, which makes PFAS very persistent, and they are therefore called “forever chemicals”. Due to their water solubility and mobility, contamination of water, soil and biota has occurred globally. In addition, some PFAS have been documented as toxic and/or bio-accumulative substances, both with respect to human health and the environment. In contrast to e.g. PCBs and PBDEs, they tend to attach to proteins, not lipid. Without taking action, their concentrations will continue to increase, and their toxic and polluting effects will be difficult to reverse.

Definition

PFAS are defined following the OECD definition[1] (https://one.oecd.org/document/ENV/CBC/MONO(2021)25/En/pdf) as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e., with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF3) or a perfluorinated methylene group (–CF2–) is a PFAS. This definition is also used in the proposal from five European countries for a EU-wide ban on PFAS. There are thousands of PFAS; the exact number cannot be quantified.

[1] OECD Environment Directorate Chemicals and Biotechnology Committee: OECD Environmental Health and Safety Publications – Series on Risk Management no. 61: Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances – Recommendations and Practical Guidance (ENV/CBC/MONO(2021)25)

The rationale for PFAS24

All PFAS under the afore mentioned OECD definition are covered by the entry of PFAS on the list of substances for priority action (LCPA). However only for a limited number of PFAS sufficient data is available to assess their environmental impact, therefore, as a pragmatic approach, the current background document explains the validity for the selection of 24 PFAS for the purpose of monitoring and environmental risk assessment. Among the 24 selected PFAS included, there are 6 perfluoroalkyl sulfonic acids, 13 perfluoroalkyl carboxylic acids, 3 perfluoroalkyl ether carboxylic acids, and 2 fluorotelomer alcohols (see table 1).

The selection of included PFAS is based on coherence with other suggested proposals/policies (revised Water Framework Directive (WFD)) (and national monitoring programs and priorisations), which are based on a relative toxicity approach, where the following parameters have been considered:

i) availability of (eco)toxicity data and physico-chemical parameters including analytical methods;

ii) availability of the relative potency factor as described in the paper Bil et al. (2021) and according to expert judgment;

iii) most recent PFAS on the market

Other PFAS than these 24 PFAS have been found to be present in the environment, and there is a possibility that replacement of PFAS in products may lead to an increase of concentration of other PFAS. However, while total PFAS concentration can be estimated using the total oxidizable precursor (TOP) assay, this approach is in the early stages of development in the case of biota. We will therefore only consider PFAS24 in this document.

Acronym	**CAS number**	**Functional groups**
PFBA	375-22-4	Carboxylic acid
PFPeA	2706-90-3	Carboxylic acid
PFHxA	307-24-4	Carboxylic acid
PFHpA	375-85-9	Carboxylic acid
PFOA	335-67-1	Carboxylic acid
PFNA	375-95-1	Carboxylic acid
PFDA	335-76-2	Carboxylic acid
PFUnA or PFUnDA	2058-94-8	Carboxylic acid
PFDoDA or PFDoA	307-55-1	Carboxylic acid
PFTrDA	72629-94-8	Carboxylic acid
PFTeDA	376-06-7	Carboxylic acid
PFHxDA	67905-19-5	Carboxylic acid
PFODA	16517-11-6	Carboxylic acid
PFBS	375-73-5	Sulfonic acid
PFPeS	2706-91-4	Sulfonic acid

PFHxS	355-46-4	Sulfonic acid
PFHpS	375-92-8	Sulfonic acid
PFOS	1763-23-1	Sulfonic acid
PFDS	335-77-3	Sulfonic acid
6:2 FTOH	647-42-7	Telomer alcohol
8:2 FTOH	678-39-7	Telomer alcohol
HFPO-DA (Gen X)	62037-80-3	Ether carboxylic acid
ADONA	958445-44-8	Ether carboxylic acid
C6O4	1190931-41-9	Ether carboxylic acid

Monitoring

The PFAS found in the environment has multiple sources, dependent on the emission of the specific substance and its precursors. The total PFAS production in the EU has been estimated to be approximately 75 000 tonnes/year[2]. The emissions to water from paper mills alone have been estimated to be between 11000 and 28000 tonnes/year[3].

Various actions are in place to tackle environmental PFAS emissions including WFD, MSFD, Stockholm convention, EFSA (EFSA 2020) and REACH with the goal to ensure high level protection of human health and the environment. This also aligns with OSPAR operational objective S2.01 on identification of contaminants of emerging concern and priorities them for action.

Substances have been found at all levels of the marine environment. Due to the large number of PFAS it is not possible to cover everything comprehensively. The PFAS-24 proposed in the PFAS EQS-dossier, is suggested to currently be a suitable level of detail but this may need revision in the future depending on the development in analytical methodology and policy development.

PFAS compounds are now ubiquitous in the environment. This is supported by monitoring data on air, water, sediment and biota (fish, mammals, seabird eggs, shellfish) documenting its spatio-temporal distribution in most compartments of the environment. Depending on physical-chemical properties different PFAS are more suitable to monitor in different matrices (short-chained: water; medium-length: biota; long-chained: sediment).

Monitoring data for PFAS is currently reported for some compartments and areas of OSPAR. Furthermore, quality assurance is in place within Quasimeme. Table presents 11 PFAS substances in biota and 1 substance (PFOS) in water (no data in sediment). It also presents compartments/matrices and concentration levels found in the OSPAR area (and reported to the ICES database). More monitoring data is available at the national level while not yet reported to ICES.

Methods for proposed Quality Standards (QS)

We have here summarized the work presented in the draft EQS dossier proposed to EU (JRC 2023): From existing evaluations, it is known that PFOS, PFOA and other PFAS have a relatively low *acute* toxicity to

[2] From ECHA 2023, Annex A
[3] Commission Staff Working Document SWD(2022) 540 final

water organisms, but they may pose a problem when entering the food chain via fish. Therefore, the analysis was mainly focused on deriving human health-based quality standards for fish consumption.

The ecotoxicity data and the hazard assessment performed in the Italian EQS dossiers drafted for **PFOA, PFBA, PFBS, PFHxA, PFPeA** (IT 2015) were fully considered in the present draft EQS dossier. For **PFOA**, also the Dutch EQS dossier (RIVM, 2017) was taken into account. In general, no further evaluation of the studies was carried out, and the MAC- and AA-QS were derived following the evaluations performed by Italy (Valsecchi et al., 2017) and RIVM (2017).

Ecotoxicity data on **PFOS** were collected from the EQS dossier of 2011, revised by the JRC in 2017. Sediment ecotoxicity data were instead retrieved from the Swiss EQSsed dossier prepared in 2020. No additional ecotoxicological data searches were performed in the present EQS dossier.

According to this literature, acute toxicity of **PFOS, PFOA, PFBA, PFBS, PFHxA and PFPeA** (LC50 and EC50) was found at the mg/L range or higher; while the chronic toxicity of **PFOS, PFOA, PFBS and PFHxA** (EC10 and NOEC) in the mg/L to ug/L range (as assessed in laboratory studies). The EQS dossier derived MAC-QSwater,eco and the AA-QSwater,eco in saltwater for **PFOS, PFBA, PFbS, PFHxA, PFPeA**. In the sediment, the dossier proposed a QS for PFOS only, and recognized that there were no sufficient data to derive a QS in sediment for **PFOA, PFBA, PFBS, PFHxA, PFPeA**.

Information on PFAS mobility and relative potency factor (RPF) are retrieved from the publication of Bil et al. (2021) for 17 PFAS. Moreover, the RPFs for 7 additional PFAS were estimated by read-across and are provided as a range because these were assumed to be in between the derived RPFs of either the perfluoroalkyl carboxylic or sulfonic acids with a shorter or a longer alkyl chain. Bil et al (2021) derived RPF using a database of liver endpoints (i.e. absolute liver weight, relative liver weight (grams absolute liver wt per 100 g terminal body wt), and liver hypertrophy (enlargement of hepatocytes)) was established for 16 PFAS, using data with the same species (rat), sex (male), and exposure route (oral) and comparable exposure duration (42–90 d).

Biological effects of PFAS in marine organisms

We have here summarized a recent and comprehensive review on PFAS in marine environment, and especially the section on biological effects (Aminot et al 2023).

Ecotoxicological tools embrace from acute exposures, usually not considering environmentally realistic concentrations, to chronic sublethal responses that do so, although mostly under controlled laboratory conditions. Tested acute aqueous exposures can consider up to mg/L, whereas environmental concentrations if these chemicals in marine waters are mostly found in the ng/L range. This review suggested that actually available data:

- Algae: positioned algae as the least sensitive biota to PFOS while fish were placed at the other end, a wide range of invertebrate groups lay in between

- Invertebrates: levels of PFOS (representing 64% 100% of all measured PFAS) in estuarine sediment (< 15 µg/kg) posed low risk to benthic species

- Fish: PFAA mixtures (PFOS, PFOA, PFNA, and PFBS) potentially disrupted the endocrine system at a multigenerational scale, as observed in the Japanese medaka (*Oryzias latipes*, Lee et al., 2017). More recently, studies with marine species include the use of “omic” approaches as more suitable for this large and diverse chemical group (Sinclair et al., 2020). Lipid degradation pathways, including upregulation of enzymes in fatty acid degradation, such as fatty acid β-oxidation, and oxidative markers such as CAT and glutathione S-transferase were significantly affected by PFAS confirming lipid homeostasis disruption in Atlantic cod *G. morhua* (low-environmental concentration intraperitoneal injection). No other significant responses were seen on gene expression (cyp1a, acox1), DNA fragmentation (Comet assay), and VTG concentration. The authors relate this discrepancy with other fish exposures to the low-environmental concentrations considered.

- Turtles/Birds/Mammals: few studies exist on biological effects of PFAS. For this group of species, the biomarkers considered should be based on the use of conservative tissues (i.e., blood), and the application of novel technologies such as “omics” is valuable. The available studies suggest a relationship between PFAS concentration (e.g. in blood) and immune system, oxidative stress status, body condition and hormone balance. These studies are based on field observation to related to low-environmental concentrations and chronic exposure.

Annex: EQS and QS tables in the draft EQS dossier (2023)

QS for human health is the “critical QS” for derivation of an Environmental Quality Standard

	Value	Comments
Proposed AA-EQS for human health [μg.kg$^{-1}_{biota\ ww}$]	0.077 μg.kg$^{-1}_{biota\ ww}$ (PFOA-equivalents)	**Critical QS is QS for human health**
Proposed AA-EQS in water [ng.L^{-1}]	4.4 ng/L for PFOA-equivalents	**See section 7.8**

Specific Quality Standard (QS)

Protection objective[4]	**Unit**	**Value**	**Comments**
Pelagic community (freshwater)	[μg.L^{-1}]	See sections 7.1, 7.2, 7.3	
Pelagic community (marine waters)	[μg.L^{-1}]		
Benthic community (freshwater)	[μg.kg^{-1} $_{dw}$]	See section 7.4	
Benthic community (marine)	[μg.kg^{-1} $_{dw}$]		
Predators (secondary poisoning)	[μg.kg$^{-1}_{biota\ ww}$] [ng.L^{-1}]	For fish and molluscs, the $QS_{biota,sec\ pois,\ fw}$ is 22.3 and 6.2 μg/kg_{ww} (PFOA-equivalents)	See section 7.7
Human health via consumption of fishery products	[μg.kg$^{-1}_{biota\ ww}$] [ng.L^{-1}]	0.077 μg/kg_{biota} for PFOA-equivalence) (0.22 ng/L for PFOA)	See section 7.8
Human health via consumption of water	[μg.L^{-1}]	0.0044 for PFOA-equivalents PFOA,	

Tentative QS_{water}	**Relevant study for derivation of QS**	**Assessment factor**	**Tentative QS - PFOA**
$MAC_{freshwater,\ eco}$	HC_5 27.8 mg.L^{-1} (13.4 – 46.9 mg.L^{-1})	10	2.8 mg.L^{-1}
$MAC_{marine\ water,\ eco}$		10 x 10	0.28 mg.L^{-1}
$AA\text{-}QS_{freshwater,\ eco}$	*Pimephales promelas* / 39 days NOEC : 0.3 mg.L^{-1}	10	0.030 mg.L^{-1}
$AA\text{-}QS_{marine\ water,\ eco}$		10 x 10	0.003 mg.L^{-1}
$AA\text{-}QS_{freshwater,\ sed.}$	-	-	- μg.kg$^{-1}_{ww}$ - μg.kg$^{-1}_{dw}$

Tentative QS_{water}	Relevant study for derivation of QS	Assessment factor	Tentative QS - PFOS
$MAC_{freshwater,\ eco}$ *	*Oncorhynchus mykiss*/ 96 h LC_{50}: 2.5 mg/l	100	0.025 mg.L^{-1}
$MAC_{marine\ water,\ eco}$		1000	0.0025 mg.L^{-1}
$AA\text{-}QS_{freshwater,\ eco}$	*Chironomus tentans* / 36-d LOEC : <0.0023 mg.L^{1}	100	0.023 µg.L$^{-1\ *}$
$AA\text{-}QS_{marine\ water,\ eco}$		100 x 5	0.0046 µg.L$^{-1\ *}$
$AA\text{-}QS_{freshwater,\ sed.}$	*Monoporeia affinis* / 22 d NOEC: 1300 µg/kg d.w.	100	13 µg.kg$^{-1}_{dw}$ (= 13.5 µg.kg$^{-1}_{dw}$ for 5% OC)

Tentative QS_{water}	Relevant study for derivation of QS	Assessment factor	Tentative QS - PFBA
$MAC_{freshwater,\ eco}$ *	*Brachionus calyciflorus* / 24 h LC_{50}: 110 mg/L	100	1.1 mg.L^{-1}
$MAC_{marine\ water,\ eco}$		100 x 10	0.110 mg.L^{-1}
$AA\text{-}QS_{freshwater,\ eco}$	No chronic toxicity data, assessment based on the lowest acute toxicity value	1000	0.11 mg.L^{-1}
$AA\text{-}QS_{marine\ water,\ eco}$		1000 x 10	0.011 mg.L^{-1}
$AA\text{-}QS_{freshwater,\ sed.}$	-	-	

Tentative QS_{water}	Relevant study for derivation of QS	Assessment factor	Tentative QS - PFBS
$MAC_{freshwater,\ eco}$ *	*Americamysis bahia* / 96 h EC_{50}: 372 mg/L	100	3.72 mg.L^{-1}
$MAC_{marine\ water,\ eco}$		1000	0.372 mg.L^{-1}
$AA\text{-}QS_{freshwater,\ eco}$	*Oryzias melastigma* / Life cycle study NOEC: 1 µg/L	10	0.1 µg.L^{-1}
$AA\text{-}QS_{marine\ water,\ eco}$		100	0.01 µg.L^{-1}
$AA\text{-}QS_{freshwater,\ sed.}$	-	-	

Tentative QS_{water}	Relevant study for derivation of QS	Assessment factor	Tentative QS - PFHxA
$MAC_{freshwater,\ eco}$ *		100	0.86 mg.L^{-1}

MAC$_{\text{marine water, eco}}$	*Scenedesmus subspicatus* / 72 h EC_{50}: 86 mg/L	1000	0.086 mg.L^{-1}
AA-QS$_{\text{freshwater, eco}}$	*Oncorhynchus mykiss* / early life-stage toxicity test NOEC: 9.96 mg/L (Burke, 2008).	50	0.199 mg.L^{-1}
AA-QS$_{\text{marine water, eco}}$		500	0.019 mg.L^{-1}
AA-QS$_{\text{freshwater, sed.}}$	-	-	

Tentative QS$_{\text{water}}$	**Relevant study for derivation of QS**	**Assessment factor**	**Tentative QS - PFPeA**
MAC$_{\text{freshwater, eco}}$ *	*Pimephales promelas* / 96 h LC_{50}: 31.8 mg/L	10	3.18 mg.L^{-1}
MAC$_{\text{marine water, eco}}$		10 x 10	0.318 mg.L^{-1}
AA-QS$_{\text{freshwater, eco}}$	No chronic toxicity data, assessment based on the lowest acute toxicity value	1000	0.0318 mg.L^{-1}
AA-QS$_{\text{marine water, eco}}$		1000 x 10	0.0032 mg.L^{-1}
AA-QS$_{\text{freshwater, sed.}}$	-	-	

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Our vision is a clean, healthy and biologically diverse North-East Atlantic Ocean, which is productive, used sustainably and resilient to climate change and ocean acidification.

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